

IUCLID Active Substance application Manual

European Food Safety Authority (EFSA)

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Introduction

REGULATORY BACKGROUND FOR CHEMICAL PESTICIDE ACTIVE SUBSTANCES APPLICATIONS

The **procedures** for approval and renewal of approval of chemical pesticide active substances are set by the **Regulation (EC) No 1107/2009**¹ concerning the placing of plant protection products on the market, as amended by **Regulation (EU) 2019/1381**², and by **Commission Implementing Regulation (EU) No 2020/1740**³ – that applies as from 27 March 2021 and replaces the previous procedure under Implementing Regulation (EU) No 844/2012⁴ – respectively.

Active substances (including microorganisms) can only be approved for use in plant protection products if they fulfil the approval criteria that are laid down in **Regulation (EC) No 1107/2009**¹. At least one use of the substances in plant protection products must be proven safe for people's health, including their residues in food, for animal health and must not have any unacceptable effects on the environment before a substance can be approved, where relevant subject to conditions or restrictions. Companies may apply for amendments of conditions of approvals, which follow the same regulatory process.

The initial approval of an active substance is valid for a limited period and the approval of an active substance needs to be reviewed periodically. A renewal of approval is only granted after the substance is re-evaluated and at that occasion, at least one safe use of the substance is demonstrated. The details of the renewal procedure are set out in **Commission Implementing Regulation (EU) No 2020/1740**³ – that applies as from 27 March 2021 and replaces the previous procedure under Implementing Regulation (EU) No 844/2012⁴.

DATA REQUIREMENTS FOR CHEMICAL PESTICIDE ACTIVE SUBSTANCES APPLICATIONS

The **data requirements** for a chemical pesticide active substance application dossier for use in plant protection product are indicated in the **Annex – part A** of the **Commission Regulation (EU) No 283/2013**⁵

1 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

2 Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

3 Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012

4 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance.

5 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

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and the **Commission Regulation (EU) No 284/2013**⁶ (“new” data requirements) setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and in the **Commission Regulation (EU) No 544/2011**⁷ and the **Commission Regulation 545/2011**⁸ (“old” data requirements) implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances.

Following the entry into force of the **Transparency Regulation** (Regulation (EU) 2019/1381²), the General Food Law has been amended by introducing **new requirements regarding transparency of submitted data**, including the **submission of the dossiers** for pesticide active substances (including microorganisms) **applications using IUCLID format**⁹.

These new requirements, as implemented by the **Practical Arrangements**¹⁰ laid down by EFSA, are reflected in the **EFSA “Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure”**¹¹ and apply to all **pesticides applications submitted as of 27 March 2021**.

The **IUCLID dossier for an active substance application** shall contain:

1. a **MIXTURE DATASET**: with data on the representative mixture (including the GAP, as a mandatory document);
2. an **ACTIVE SUBSTANCE DATASET**: with data on the TARGET active substance;
3. (if appropriate) **one/several METABOLITE dataset(s)**: with data on the relevant metabolite(s)
4. (if appropriate) **one/several OTHER SUBSTANCES** relevant FOR ASSESSMENT **dataset(s)**: with data on any substance of concern (e.g. relevant impurities).

Note: the table of contents is identical for metabolite and other substance datasets

Applicants are required to create a new “Mixture” dataset and select the Working context ‘**EU PPP Active substance application (product)**’.

Safeners, synergists and co-formulants can be entered in the Mixture composition document (Section 1.4) as “reference substances” even when they are mixtures (e.g. a co-formulant dissolved in a solvent).

⁶ Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance

⁷ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances

⁸ Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products

⁹ Ref: Commission working document under revision

¹⁰ <https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements>

¹¹ <https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance>

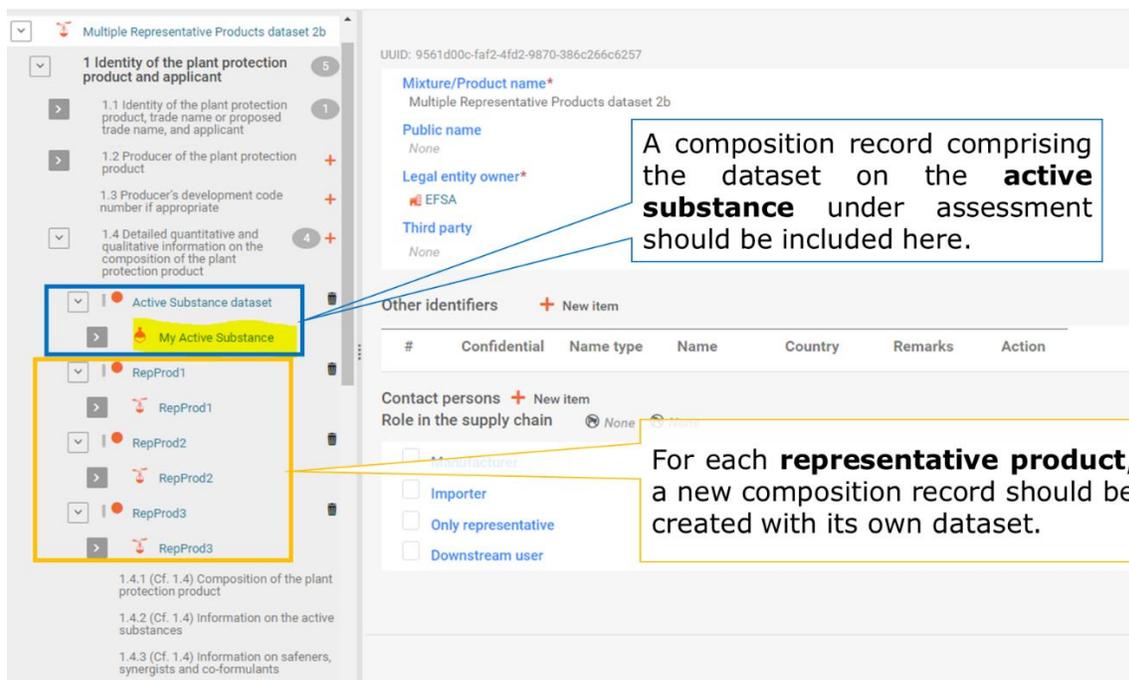
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Information on the alternative co-formulants should be entered similarly to other co-formulants. Relevant MSDSs can be inserted in the section “summary and evaluation” as Literature Reference entities.

For reporting **metabolites** follow the information in the [FLEXIBLE_SUMMARY.Metabolites](#) document.

In case of **multiple representative products**, the notifier(s) should create in the **product composition section** (1.4 - Detailed quantitative and qualitative information on the composition of the preparation):

- a **composition record** comprising the **active substance** dataset;
- a **separate composition record** for each representative product, each one including its own **product dataset**. It is recommended to name each record very clearly, and to include a relevant product type in the name.



Multiple Representative Products dataset 2b

1 Identity of the plant protection product and applicant

1.1 Identity of the plant protection product, trade name or proposed trade name, and applicant

1.2 Producer of the plant protection product

1.3 Producer's development code number if appropriate

1.4 Detailed quantitative and qualitative information on the composition of the plant protection product

Active Substance dataset

My Active Substance

RepProd1

RepProd1

RepProd2

RepProd2

RepProd3

RepProd3

1.4.1 (Cf. 1.4) Composition of the plant protection product

1.4.2 (Cf. 1.4) Information on the active substances

1.4.3 (Cf. 1.4) Information on safeners, synergists and co-formulants

UUID: 9561d00c-faf2-4fd2-9870-386c266c6257

Mixture/Product name*
Multiple Representative Products dataset 2b

Public name
None

Legal entity owner*
EFSA

Third party
None

Other identifiers + New item

#	Confidential	Name type	Name	Country	Remarks	Action
---	--------------	-----------	------	---------	---------	--------

Contact persons + New item

Role in the supply chain None Manufacturer Importer Only representative Downstream user

A composition record comprising the dataset on the **active substance** under assessment should be included here.

For each **representative product**, a new composition record should be created with its own dataset.

Following the Table of Content, applicants are required to:

1) report data in the **relevant IUCLID documents** (Endpoint summaries, Endpoint study records, Flexible records, Flexible summaries, etc). The detailed crosswalks from the EU Table of Contents

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(SANCO/10181/2013) for chemical plant protection product (PPP) dossiers to IUCLID 6.5 has been published on EFSA knowledge junction ([EFSA, 2021a](#)¹²);

2) in line with the provisions of the Transparency Regulation, provide **full study reports** (including publications and QSAR, QMRF or QPRF reporting forms) as literature reference entities and other **supporting materials** (e.g. excel templates) as attached documents.

For each document provided, applicants must submit:

- **Always:** a non-confidential version (for public disclosure) with all elements claimed to be confidential blackened (public version).
- **In case there is a difference with the public version:** a confidential version (not for public disclosure) with all information visible and no blackening applied. In this version, all information claimed to be confidential by the applicant should be boxed or earmarked. For excel, XML and similar types of attachments for example the primo or animal burden calculators only the public version should be provided, except for rare cases.

For details on copyright rules please see section “Data source (Literature Reference)– common block” section of this manual.

When no data is submitted, a **justification for data waiving** is needed as the validation tool of IUCLID will check for completeness of the mandatory sections according to the validation rules indicated in this manual.

Direct instructions on the **compilation of the fields** of each of the IUCLID entities are given in this manual in the relevant IUCLID dossier section.

Instructions provided for the Active substance dataset are applicable also to the Metabolite dataset and to Other substances for assessment dataset.

The dataset where a study is to be completed is **dependent on the test material**. All the studies should generally be reported only once. In case of studies including parent and metabolites the following approaches should be used:

- If the test material is the **parent substance**, studies should be included under the **parent dataset**.
- If the test material is the **metabolite**, studies should be reported under the **metabolite dataset**.
- If the test material is a **mixture of parent and metabolite** studies should be reported under the **parent dataset**
- If the test material is a **mixture of metabolites**, the studies should be reported under the **predominant compound dataset**

¹² European Food Safety Authority (EFSA). (2021a). Crosswalks IUCLID 6.5 EU PPP Active substance application (product) to KCA&KCP [Data set]. Zenodo. <https://doi.org/10.5281/zenodo.4312895>

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- If there are several test material in one study, it is needed to identify the main tested compound as the “test material”, and the study should be included under the main tested compound dataset

Direct instructions on **where to include individual supporting documents** are provided in the applicable chapter of this manual and in the section hereafter on the “overview of the main cases”.

Any additional documents not specifically required in the respective sections of this manual can be attached, either to the “Dossier header” section (for administrative documents only) or the “Summary and Evaluation” document at the end of the dataset (Section 11 in the active substance dataset, Section 13 in the Product dataset).

The dossier header should only be used to upload administrative documents. The motivation and the nature of the attachments should be specified in the remark fields of the attachment.

The Summary and Evaluation document should be used to upload any additional reports that further facilitate the assessment of the dossier. The nature of the report should be specified in the field “type or report”. See also specific instructions in the dedicated Chapters on “dossier header” and on Section 11 (active substance) and Section 13 (Product) of the present manual.

MRL DOSSIERS SUBMITTED AS PART OF AN ACTIVE SUBSTANCE APPROVAL OR RENEWAL PROCESS

As explained in the Administrative guidance¹³, when the applicant submits an MRL dossier as part of an approval or renewal process, a separate dossier (EU PPP MRL application) should be created in IUCLID. The dossier supporting the approval or renewal process and the one supporting the MRL application should be provided at the same time but submitted separately in the EFSA central submission system¹⁴.

As for any stand-alone MRL application, the purpose of the MRL application submitted as part of the peer-review should be indicated in the dossier header of the MRL dossier following the instructions in IUCLID. The link between the active substance dossier and the MRL dossier should be indicated in both dossier headers (i.e. active substance and MRL). In the dossier headers, the applicant should tick the check box under the section “Other submission related information” and specify the submission number of the other dossier (please also refer to the dedicated Chapter on MRL Dossier header in the [MRL applications Manual](#)).

Further specific instructions are given in the section hereafter on the main cases of MRL dossiers submitted AS PART OF approval/renewal of the active substance:

¹³ Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure <https://www.efsa.europa.eu/it/supporting/pub/en-6464>

¹⁴ For technical reasons, the MRL submission will have to be done before the dossier submission to allow the system to link the two items.

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1. Setting specific maximum residue level(s) or changing current EU MRLs (under the approval/renewal dossier):

a: If the **GAP(s) relevant for the MRL dossier is/are identical to the representative use(s)** of the approval/renewal dossier, it is **not required to create a separate MRL dossier**. In such case, the MRL proposal(s) can be directly derived in the approval/renewal dossier, highlighting the rationale of the proposed new MRLs in the endpoint summary 6.7.2.

The fact that MRL changes are proposed in the dossier (based on the representative uses assessed in the dossier) may be simply highlighted in the dossier header, as a remark under the purpose of the application:

Purpose of the application

?

X

All background information linked to the existing MRL in EU shall be reported in Section 11.1 (Assessment from other Authorities: Assessments in Europe). See also specific instructions in the dedicated Chapter 11.1 of the MRL applications manual.

b: If the **GAP(s) relevant for the MRL dossier is/are different compared to the representative use(s)** of the approval/renewal dossier, **a separate MRL dossier is required**. Respective GAP documents must be created in the approval/renewal dossier and in the MRL dossier.

In the MRL dossier submitted as part of the approval/renewal, it is not required to submit all the studies already submitted in the approval/renewal dossier. However, the dataset created for the approval/renewal dossier can be reused. The core studies (e.g. storage stability studies, metabolism studies, toxicological studies) related to the approval/renewal of the active substance should be included in the approval/renewal dossier. This can be repeated in the MRL dossier. However, the study records that are specifically linked to the MRL dossier (e.g. studies on magnitude of residues in plant commodities related to GAPs for which MRLs are proposed), should only be included in the MRL dossier.

All endpoint summaries should be addressed separately in each dossier. Typically, the core endpoints of Section 6.1 (storage stability) and Section 6.2 (metabolism in plants, rotational crops and livestock) should be exhaustively summarised in the approval/renewal dossier, considering all the available studies. In the MRL dossier, a copy/paste of these endpoint summaries can be made for these sections (6.1 and 6.2) but a statement as to whether those sections were sufficiently elucidated in the context of the MRL dossier has to be made in the respective endpoint summaries of the MRL dossier. Furthermore, the endpoint summaries of Sections 6.3 (magnitude of residues in plants), 6.4 (magnitude of residues in livestock

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commodities), 6.5 (effect of processing), 6.7 (proposed residue definitions and MRLs), 6.9 (dietary exposure), 6.10.1 (effect on residue level in pollen and bee products) should be compiled for the specific scenario of the MRL dossier.

2. Evaluation of **confirmatory data following review according to Article 12** (under the renewal dossier):

The submission of confirmatory data for art.12 **should be done in a separate MRL dossier**, using the relevant purpose of application in the dossier header of the EU PPP MRL application. This option gives the possibility to the applicant to clearly identify the GAPs to be assessed for the MRL assessment and to report specific studies (e.g. residue trials) outside the core active substance dossier. The GAPs can be the same as the ones assessed in the reasoned opinion on the MRL review or adjusted GAPs, as defined in the “COMMISSION WORKING DOCUMENT on the evaluation of data submitted to confirm MRLs following the review of existing MRLs”¹⁵.

The data gaps identified in article 12 review for the core studies (e.g. metabolism study) should be addressed in the approval/renewal dossier and there is no need to repeat those study records in the MRL dossier. However, applicants should use the respective endpoint summaries of the MRL dossier to clearly state which data gaps of the MRL review were addressed or not addressed. This exercise of checking which data gaps of the MRL review have been addressed should be done in the MRL dossier.

The background information linked to the existing MRL in EU shall be reported in Section 11.1 (Assessment from other Authorities: Assessments in Europe). See also specific instructions in the dedicated Chapter 11.1 of the MRL applications manual.

3. **Amend existing residue definition** (under the renewal dossier):

If the assessment of the renewal of an active substance triggers the need to modify the previous residue definitions, this should be highlighted directly in the endpoint summary of Section 6.7.1 (proposed residue definitions) **of the renewal dossier**. There is **no need to submit a separate MRL dossier** in IUCLID.

When a change of residue definition is proposed, it highlighted that the existing residue definitions shall be reported in Section 11.1 (Assessment from other Authorities: Assessment in Europe). See also specific instructions in the dedicated Chapter 11.1 of the MRL applications manual.

4. Include an active substance in **Annex IV** (under the approval/renewal dossier):

If the assessment of the approval/renewal of an active substance leads to a proposal to include an active substance in Annex IV of Regulation 396/2005, this should be highlighted directly in the endpoint

¹⁵ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_sanco-10235-2016.pdf

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summaries (Section 6 and Section 6.7.2) **of the approval/renewal dossier**. In such case, there is **no need to submit a separate MRL dossier** in IUCLID.

5. Setting **import tolerances** (under the approval/renewal dossier):

The submission of an import tolerance (IT) request **should be done in a separate MRL dossier**, using the relevant purpose of application in the dossier header of the EU PPP MRL application. This option gives the possibility to the applicant to clearly identify the GAPs to be assessed for the IT request and to report specific studies (e.g. residue trials) outside the core active substance dossier.

For IT requests, it highlighted that all background information linked to the assessment in the third country (evidence of registration in the exporting country, residue definition in the exporting country, existing MRL in exporting country, legislation in the third country, etc), shall be compiled in Section 11.1 (Assessment from other Authorities: Assessments outside Europe). See also specific instructions in the dedicated Chapter 11.1 of the MRL applications manual.

INFORMATION IN THE PURPOSE TEXTBOXES

OECD harmonised templates (OHTs) are designed to be used in a wide range of regulatory contexts. More information on OHTs can be found on the [OECD website](https://www.oecd.org/ehs/templates/)¹⁶. For EU_PPP these documents are used in the different datasets and for microorganism and/or chemicals. For each endpoint study summary and endpoint record there is a 'Purpose' text box indicating the regulatory data requirement/s covered by the document. It can also include specific instructions that in some cases can be valid either for microorganisms or for chemicals (depending on the working context), see example below:

Acute toxicity oral

Chemical Active: The acute oral toxicity of the active substance shall always be reported.

Chemical Product: A test for acute oral toxicity shall be carried out, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.

Microorganism Active: The acute oral toxicity study should permit the identification of effects following a single exposure to the microorganism, including an assessment of toxicity, pathogenicity and infectiveness, and evaluation of the clearance of the microorganism.

Microorganism Product: An acute oral test with the plant protection product shall always be carried out only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008.

¹⁶ <https://www.oecd.org/ehs/templates/>

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OUTDATED DOSSIER FILES MAPPING INTO IUCLID

The detailed crosswalks from the EU Table of Contents (SANCO/10181/2013) for chemical plant protection product (PPP) dossiers to IUCLID 6.5 has been published on EFSA knowledge junction ([EFSA, 2021a¹²](#)). The crosswalk file includes two spreadsheets, containing the mappings for active substance (as laid out in Commission Regulation (EU) No 283/2013) and representative product (Commission Regulation (EU) No 284/2013).

The mapping of **documents A-J** is explained in the crosswalks^{12Error! Bookmark not defined.}. Document **D** will be created in IUCLID using the report generator, document **F** is dismissed.

The report generator should be used to create **documents M, N** and **L** when the appropriate report format (ftl file) is available. **Document M** on **Physical-chemical properties** (section 2) and **Toxicology** (section 5 for active substance, 7 for product) are available in April 2021 IUCLID release; **Document M** on **Ecotoxicology, Residues, and Fate and behaviour in the Environment** have been published in Zenodo, together with Phys-chem and Tox as well ([EFSA, 2021b¹⁷](#)).

Documents N1-3 and **N-5** shall be uploaded in the “Summary and evaluation” document. Information on how to complete a ‘Summary and Evaluation’ document is shown below.

Document N-4 corresponds to “Relevance of metabolites in ground water” (**Section 7.6** in the Metabolites dataset).

Document O is dismissed by validation assistant.

FLEXIBLE SUMMARY.SummaryEvaluation EU PPP			
Name	Instructions	Type	Field Path
Administrative data		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdministrativeDataSummary.DataProtection
Reports and administrative information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo
Reports and administrative information			FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo

¹⁷ European Food Safety Authority (EFSA). (2021b). Documents M EU PPP for IUCLID Report Generator. Zenodo. <https://doi.org/10.5281/zenodo.4748404>

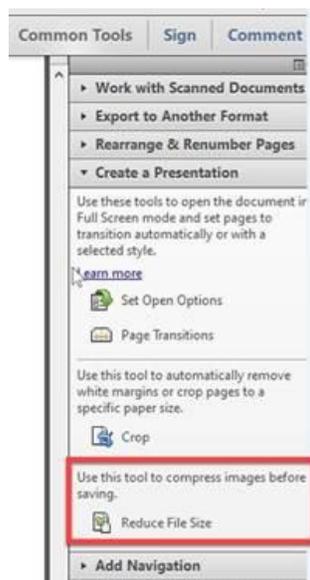
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Type of report	Indicate the type of document that has been uploaded e.g. 'Document C Existing or proposed labels'	Multi-line text	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.TypeOfReport
Attached document	If the file or document uploaded in the 'Attach one or more documents including the sanitised version of the document' contains redacted information upload the original version in this field.	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.AttachedDocument
Attached (sanitised) document for publication	Upload sanitised version of files or documents which could not be uploaded in other sections of the dossier. This would include 'Document C Existing or proposed labels' 'Document G Permission of each formulant in accordance with EU legislation' 'Document I Other data on the formulants' Documents M, N and L - report generator should be used to create these documents when the appropriate report format (ftl file) is available	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.SanitisedDocument
Reports and administrative information			
Other references (including SDS)	Link to other reports not referenced in the endpoint study records needed to support the assessment. The bibliographic information should be completed and the PDF uploaded in the literature reference entity This would include: 'Safety datasheets' 'Scientific opinions of national/international regulatory bodies'	Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS
References		Literature reference list	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS.References
Additional information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation
Additional information	Overall summary of the main conclusions for the substance or mixture can be entered here	Rich text area	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation.AdditionalInformation

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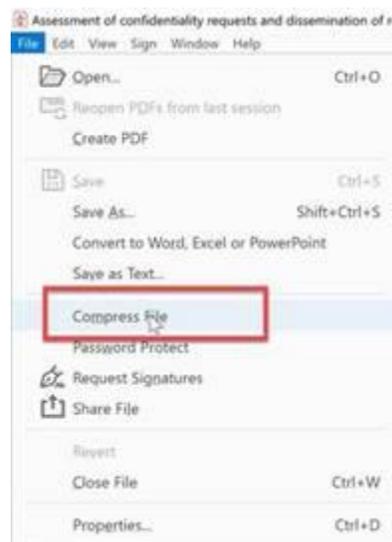
HOW TO REDUCE THE FILE SIZE OF ATTACHMENTS

1. Generate the attachment report for the dossier / dataset to be submitted to get an overview of all the attachments
 - a. A generic attachment report that generates a .csv file (that can be opened in Excel) and lists all attachments with their size and type is available.
2. Identify all the PDF attachments that have an unreasonably large size (e.g. >100MB)
3. Download the large PDF attachments and use Adobe features to reduce the PDF file size
 - a. In the past this feature was called *“Reduce File Size”* in Adobe



- b. In latest Adobe you can find the following menu item: *“Compress File”*

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4. Upload smaller version of the PDF as attachment to the dataset

This approach can be applied to PDF attachments only, though similar size reduction solution can be applied for other attachment types as well: e.g. extremely large images (with some loss in resolution quality).

JOINT SUBMISSION AND SHARING OF STUDIES

According to Art. 5(2) of Commission Implementing Regulation (EU) No 2020/1740, “where there is more than one applicant requesting the renewal of the approval of the same active substance, those applicants shall take all reasonable steps to submit their dossiers jointly.” In light of the above, companies submitting a renewal of approval of the same substance, shall reach an agreement on sharing studies and data within a Joint Submission. There are two main types of Joint Submission: 1) joint submission with a third-party representative and a number of member applicants. This third-party representative could be e.g. a consultant. 2) joint submission with a lead applicant and a number of member applicants j.

In the situation 1), the consultant is expected to submit a renewal dossier with all joint information (including all studies to be evaluated) as well as confidential information of each member of the joint submission.

In the situation 2) the lead applicant is expected to submit a renewal dossier which includes joint information submitted by the lead on behalf of all the members including all studies to be evaluated and presented in (robust) study summaries. In addition, the lead applicant would also add his own confidential information in the main lead dossier. All other members would submit supplementary renewal dossiers including only the confidential information. This covers, for example, information about the

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manufacturer, the sites, analytical methods, mixture composition and substance composition information.

Letter of Access

In relation to sharing of studies among companies which own separate data and which give data citation rights (Letter of Access) to each other for active renewal purposes, the approach would be as follows.

To indicate that a Company has a letter of access follow these instructions in relation to the “Data Source (Literature Reference)” compilation:

- In the reference field: indicate the data is linked to a letter of access
- In the data access field: indicate that data submitter has letter of access
- In the data protection claimed field: indicate data protection was claimed by the data owner
- In the Attached document field: upload the letter of access
- In the Attached (sanitised) document for publication: upload the sanitised study report

Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants

a) Categories of IUCLID fields and associated filter rules

As a general rule, information inserted in IUCLID fields is automatically disclosed by EFSA when the application is deemed admissible, unless a confidentiality request is submitted by applicants on IUCLID fields where this is permitted and the confidential status is granted by EFSA or the Rapporteur Member State where applications submitted for the approval of a new active substance or the amendment to the conditions of approval of active substances are concerned. Confidentiality requests are permitted with regard to fields that correspond to the items listed in Article 63 of Regulation EC No 1107/2009.

These are:

- the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
- commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
- commercial information revealing sourcing, market shares or business strategy of the applicant;
- quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;
- the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities;

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- results of production batches of the active substance including impurities; and
- information on the complete composition of a plant protection product.

Each IUCLID field has been assigned a **filter rule** which establishes whether the associated information is published or not (see column B in the filter rule excel file) available here: <https://zenodo.org/record/4627148#.YFig969KiUk>. Fields that are published by default are governed by the filter rule “**PUBLISHED**”. Fields for which the applicant can submit a confidentiality request are subject to the filter rule “**UNLESS_CONF**”.

Please note that fields subject to the “**UNLESS_CONF**” rule will be published on the OpenEFSA Portal, unless a confidentiality request has been submitted by the applicant and accepted by EFSA or the RMS pursuant to EFSA’s [Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation \(EC\) No 1107/2009](#).

To claim certain fields subject to the filter rule “**UNLESS_CONF**” confidential, the applicant must:

- set a **confidentiality flag** in the designated field pertaining to the relevant IUCLID entity, summary, record or section (CBI - confidential business information should be selected as this is in alignment with the transparency regulation), and
- submit a **justification** for each confidentiality request in compliance with the standards set out in the Practical Arrangements.

More specifically, the applicant must provide at least the following elements:

(a) a clear identification of the relevant parts of the submitted information that the applicant considers eligible for confidential treatment. This implies that the **specific parts of the text actually considered confidential** must be **indicated**;

(b) a text explaining comprehensively and in plain language the reason(s) why the information should be granted confidential status, including whether:

(i) the document, information or data for which confidentiality status is requested is not publicly available or is known only to a limited number of persons;

(ii) the public disclosure of the document, information or data for which confidentiality status is requested may potentially harm the interests of the applicant to a significant degree;

(iii) explanation or evidence demonstrating that the harm that may be caused is of a significance corresponding at least to 5% of the total gross annual turnover for legal persons, or the gross annual earnings for natural persons, for the financial year preceding the submission of the confidentiality request. If the harm is quantified as not reaching this percentage, or the applicant is unable to calculate its impact on their turnover/earnings,

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the applicant must provide specific reasons as to why they considered that public disclosure would potentially harm their interests to a significant degree;

(iv) the document, information or data for which confidential treatment is requested is eligible for legal protection and has not been acquired in an unlawful manner;

(v) the document, information or data for which confidentiality status is requested has been finalised in the form submitted to the rapporteur Member State / EFSA up to five years prior to the submission of the confidentiality request. If the document, information or data deemed to be awarded confidential status is older than five years, the rapporteur Member State shall ensure that the applicant provides specific reason on why public disclosure of that information would still potentially harm its interests to a significant degree.

The filter rule governing data protection fields is titled “**DATA_PROTECTION**”. Confidentiality flags in the data protection field will be published, if they were activated by the applicant. This will allow the public to know that certain information to which the confidentiality flag relates have been claimed confidential by the applicant. A confidentiality flag may relate to a whole IUCLID entity, summary, record or to a (sub-)section thereof. However, the justification associated with the activated confidentiality flag will not be published.

There are four further filter rules applicable to a limited number of fields:

- “**TM_DETAILS_PPP**”: fields subject to this filter rule are located in the Test Materials entity. Information contained in these fields is published, unless they have been claimed confidential. To claim fields subject to this filter rule confidential, a **confidentiality flag** must be set in the Administrative data block in the Endpoint Study Record and a **justification** must be provided complying with the standards mentioned above in relation to the filter rule “UNLESS_CONF”.
- “**STUDY_REF_AUTH_PPP**”: fields subject to this filter rule are located in the Literature entity. If these fields contain names of authors of **unpublished** studies, they are not published to ensure protection of **personal data**.
- “**STUDY_REF_PPP**”: fields subject to this filter rule are located in the Literature entity. If these fields concern names and addresses of natural persons **involved in testing on vertebrate animals** or in **obtaining toxicological information**, they are not published to ensure protection of **personal data**.

“**NOT_PUBLISHED**”: information contained in fields subject to this filter rule is not published. This is the case for all fields with the field name “AttachedDocument”¹⁸ and “AttachedStudyReport”. These fields are reserved for the confidential versions of documents and/or study reports

¹⁸ With the exception of the field with the path description “FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.AttachedDocument” which is published in accordance with the filter rule “PUBLISHED”, since no corresponding field with the field name “AttachedSanitisedDocsForPublication” exists. This does not mean that information regarding the description of the substance composition cannot be claimed confidential.

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pertaining to the relevant IUCLID entity, summary or record. Conversely, fields with the field name *“AttachedSanitisedDocsForPublication”* are published by default, as they are governed by the filter rule **“PUBLISHED”**. A document must always be provided under the header for sanitised attachments and, only if there are any differences, a full document can also be attached.

b) General considerations underlying the setting of filter rules

Generally speaking, the number of fields that can be claimed confidential is more limited in endpoint **summaries** compared to flexible/endpoint study **records**. The underlying rationale is that endpoint summaries contain information that is key to the safety assessment and should therefore, in principle, not include a considerable proportion of information that is claimed confidential. Similarly, the possibility for applicants to claim fields confidential is **more restricted** in endpoint study records/flexible records with clear **safety** (e.g. *“ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.”*) and/or **environmental implications** (e.g. *“ENDPOINT_STUDY_RECORD.ToxicityToBirds.”*). That being said, information contained in a number of fields, including **open text fields** such as *“Remarks”* or *“AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation”* as well as in **fields allowing for the upload of documents** can **typically always be claimed confidential** – be it in flexible/endpoint study records or endpoint summaries. In other words, for each and every endpoint and data requirement there will be a possibility to claim certain information confidential.

c) Participation in EFSA’s confidentiality decision making

Applicants have several opportunities to participate in the decision-making process regarding confidentiality requests made on their renewal dossiers and to put forward their views and observations, namely:

- a. prior to the adoption of a decision rejecting the applicant’s confidentiality request in part or in full, by being consulted on the draft decision;
- b. after the adoption of a confidentiality decision, by making use of the possibility of submitting a confirmatory application;
- c. after the adoption of a decision on a confirmatory application, by having the possibility of bringing an action for annulment against the decision on the confirmatory application pursuant to Article 263 of the Treaty on the Functioning of the European Union.¹⁹

A comprehensive description of applicable procedures and provisions is available in [EFSA’s Practical Arrangements concerning transparency and confidentiality](#).

¹⁹ Consolidated version of the Treaty on the Functioning of the European Union. OJ C 326, 26.10.2012, p. 47–390.

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Comparable procedural guarantees are also provided by the responsible RMS for confidentiality requests made on their dossiers for new active substances. For further information, please check [EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation EC No 1107/2009](#), and contact the RMS responsible for the application.

d) Publication of dossier

Information not meant to be published, e.g. names of authors of unpublished vertebrate studies, along with information claimed to be confidential, is removed from the dossier, in accordance with the above-mentioned filter rules. The non-confidential version of the dossier is then made available via the OpenEFSA Portal. Dossier filtering is an automated process and it is independent of the text provided in a certain field. Therefore, it is important for applicants to review their dossier before submission via the dissemination preview feature.

Applicants should take note of the fact that a revised version of the dossier will be made available via the OpenEFSA Portal, if EFSA disagrees with one or more confidentiality requests initially submitted.

IUCLID ACTIVE SUBSTANCE APPLICATION MANUAL

EU PPP Active substance for Mixtures

Purpose:

The dossier header contains administrative data and information about the type and purpose of the application. Information in the dossier header is used by IUCLID tools to process the dossier, for example different validation assistant scenarios could be applied depending of the selection of the purpose of the application

DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES– v.3.2 (Final) [June 2021]			
Name	Instructions	Data type	Field Path
Dossier template		Header 1	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.DossierTemplate
Name		Read-only	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.DossierTemplate.Name
Version		Read-only	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.DossierTemplate.Version
Dossier name (given by user)	Short name for the dossier (this should be maintained in all versions). Refer to the active substance name in the text.	Text	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.DossierTemplate.NameGivenByUser
Dossier subject		Header 1	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.DossierSubject
Dossier subject	System information	Read-only	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.DossierSubject.Name
Submitting legal entity	System information	Read-only	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.DossierSubject.SubmittingLegalEntity
Dossier creation date/time	System information	Read-only	DOSSIER.EU_PPP_MICROORGANISMS_FOR_M

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			IXTURES.DossierSubject.DossierCreationDateTime
Dossier submission remark	The EFSA question number if allocated can be reported in this field. e.g. EFSA-Q-2021-00475. If the submission contains 'Confirmatory Information' indicate this clearly using the text 'Confirmatory Information'	Text area	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.DossierSubject.DossierSubmissionRemark
Used in category		Read-only	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.DossierSubject.UsedInCategory
Active substance approval		Header 1	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.ActiveSubstanceApproval
European reference number	Contains the unique number to identify all versions of a dossier submitted under a regulatory action. This is a UUID generated from IUCLID From the 1 May it will be possible to generate the UUID within the IUCLID application. Prior to this, a UUID can be generated using this website https://www.uuidgenerator.net/ and pasted into this field.	Text	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.ActiveSubstanceApproval.EuropeanReferenceNumber
Purpose of the application	Only one context can be listed as the purpose of the application. If 'Amendment of the approval conditions for an active substance' is	Closed list with remarks (2000)	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.ActiveSubstanceApproval.ApplicationPurpose

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	selected, provide the justification for an amendment of the approval conditions for an active substance in the remarks.		
Joint application	<p>If the purpose of the application is 'renewal of an active substance for use in plant protection products' then whether the submission is a 'Joint application' must be indicated.</p> <p>If 'no' is selected then a justification must be provided in the 'remark'</p> <p>If 'yes' provide a UUID for the joint submission and the Legal entity name for the main dossier</p>	Closed list with remarks (2000)	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.ActiveSubstanceApproval.JointApplication
Rapporteur Member State (RMS)	Indicate the Member State assessing the dossier.	Closed list with remarks (2000)	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.ActiveSubstanceApproval.RapporteurMemberState
Competent authority	Provide the name of the competent authority providing the assessment report	Multi-line text	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.ActiveSubstanceApproval.CompetentAuthority
Co-RMS	Indicate the Member State(s) acting as the co-rapporteur	Multi select closed list	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.ActiveSubstanceApproval.CoRms
Notification of studies		Header 1	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.NotificationOfStudies
Pre-application identification			DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.NotificationOfStudies.PreApplicationId

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Pre-application identifier	Enter any pre submission identifiers issued whilst notifying studies for inclusion in regulated product dossiers relevant for this dossier subject.	Text	DOSSIER.EU_PPP_MIC ROORGANISMS_FOR_M IXTURES.NotificationOf Studies.PreApplicationI d.PreApplicationId
Pre-application identification			
Studies requiring NoS justification			DOSSIER.EU_PPP_MIC ROORGANISMS_FOR_M IXTURES.NotificationOf Studies.StudiesReqJusti fication
NoS ID	List all Notification of Studies identifiers which are present in the database linked to the Pre-application identifiers (see above) but are not included in the dossier.	Text	DOSSIER.EU_PPP_MIC ROORGANISMS_FOR_M IXTURES.NotificationOf Studies.StudiesReqJusti fication.NosId
Justification	Justification for the absence of the NoS ID in the dossier	Multi-line text	DOSSIER.EU_PPP_MIC ROORGANISMS_FOR_M IXTURES.NotificationOf Studies.StudiesReqJusti fication.Justification
Studies requiring NoS justification			
Attached information		Header 2	DOSSIER.EU_PPP_MIC ROORGANISMS_FOR_M IXTURES.NotificationOf Studies.AttachedInform ation
Attachment			DOSSIER.EU_PPP_MIC ROORGANISMS_FOR_M IXTURES.NotificationOf Studies.AttachedInform ation.Attachment
Attachment	Attached administrative documents to support the application. Documents with confidential or personal information	Single file attachment	DOSSIER.EU_PPP_MIC ROORGANISMS_FOR_M IXTURES.NotificationOf Studies.AttachedInform ation.Attachment.Attac hment

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	<p>should not be attached here (e.g. letters). Remarks are used to indicate the topic/reason for including the attachment</p> <p>The Summary and Evaluation document should be used for including confidential attachments in the dossier. This is recommended as these documents foresee the possibility to upload confidential and non-confidential/sanitised versions of the same attachment.</p> <p>Scientific information should be uploaded into documents in the Table of Contents of the dossier</p>		
Remarks	Specify the motivation and the nature of the attachment.	Text area	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.NotificationOfStudies.AttachedInformation.Attachment.Remarks
Attachment			

Links to support materials:

Administrative guidance on submission of dossiers and assessment reports for the peer review of pesticide active substances

1 Identity of the plant protection product and applicant

1.1 Identity of the plant protection product, trade name or proposed trade name, and applicant

Purpose:

This document covers the data requirements:

Applicant and contact person

Trade name or proposed trade name and producer's development code number of the plant protection product if appropriate

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Mixture v.6.4 (Final) [August 2020]			
Name	Instructions	Data Type	Field Path
Mixture/Product name	This must be completed; this information is also included in the dossier header as 'Dossier subject'	Multi-line text	MIXTURE.MixtureName
Public name	Public name of the mixture	Multi-line text	MIXTURE.PublicName
Other identifiers	All former and current trade names and proposed trade names and development code numbers of the plant protection product/preparation shall be provided. Flags can be used to indicate if the trade name is confidential		MIXTURE.OtherNames
Confidential		Confidentiality	MIXTURE.OtherNames.Protection
Name type		Open list	MIXTURE.OtherNames.NameType
Name		Multi-line text	MIXTURE.OtherNames.Name
Country		Multi select open list	MIXTURE.OtherNames.Country
Remarks		Text area	MIXTURE.OtherNames.Remarks
Other identifiers			
Legal entity flags		Confidentiality	MIXTURE.OwnerLegalEntityProtection
Legal entity owner	This must be completed; this information is also included in the dossier header as 'Submitting Legal Entity'.	Entity reference field	MIXTURE.OwnerLegalEntity

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	When submitting a dossier through the Submission Portal the same legal entity should be used, 3 third party consultants may do this as foreign entities. For task forces, the lead applicant can act as the legal entity. Links the dossier to the Legal entity of the dossier owner.		
Third party flags	Option to link to the legal entity of a third party	Confidentiality	MIXTURE.ThirdPartyProtection
Third party		Entity reference field	MIXTURE.ThirdParty
Contact persons	Link to the relevant Contact entity. The primary contact point for the dossier should be provided, name, position, telephone and e-mail address		MIXTURE.ContactPersons
Person flags		Confidentiality	MIXTURE.ContactPersons.DataProtection
Person	See Legal Entity (including contact person)	Entity reference field	MIXTURE.ContactPersons.ContactPerson
Contact persons			
Role in the supply chain	Check 'Manufacturer' to indicate the applicant is the Producer of the plant protection product	Header 1	MIXTURE.RoleInSupplyChain
Role flags		Confidentiality	MIXTURE.RoleInSupplyChain.RoleProtection
Manufacturer		Check box	MIXTURE.RoleInSupplyChain.Manufacturer
Importer		Check box	MIXTURE.RoleInSupplyChain.Importer
Only representative		Check box	MIXTURE.RoleInSupplyChain.OnlyRepresentative

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Downstream user		Check box	MIXTURE.RoleInSupply Chain.DownstreamUser
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Links to support materials:

[Legal entity](#)

1.2 Producer of the plant protection product

Purpose

The name and address of the manufacturer of the preparation and of each micro-organism in the preparation must be provided as must the name and address of each manufacturing plant in which the preparation and microorganism are manufactured.

A contact person must be provided for each manufacturer.

FLEXIBLE_RECORD.Suppliers – v.4.0 (Final) [July 2018]			
Name	Instructions	Data Type	Field Path
	Set the confidentiality flag and regulatory purpose. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.Suppliers.DataProtection
Manufacturer / Importer / Formulator		Header 1	FLEXIBLE_RECORD.Suppliers.ManufacturerImportForm
Name	Indicate the name of the Supplier. Click the Link button to select the Supplier and establish the link. If the desired Supplier is not present in your database, click the New button. It will trigger the opening of the Legal entity creation dialogue. The Supplier is created and simultaneously	Entity reference field	FLEXIBLE_RECORD.Suppliers.ManufacturerImportForm.LegalEntity

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	<p>linked to the Substance or Mixture/Product dataset. To complete the information of this newly created Legal entity, click the Goto button</p> <p>The modifications will be automatically updated by clicking the Save button . The Back button button will lead back to section 1.7 Suppliers. The link can be deleted by clicking the Delete button .</p>		
Remarks		Text area	FLEXIBLE_RECORD.Suppliers.ManufacturerImportForm.Remarks
Only representation information		Header 1	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo
Assignment from non EU manufacturer	<p>Insert the official assignment documentation from the non EU-manufacturer. Click the Attachment button and the green Plus button in the context menu appearing. Specify the path and the name of the file to be inserted and indicate any remarks if useful in the Properties window.</p>	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.NonEUManufacturerAssignment
Other importers	<p>The other Importers of the same substance, from the same non EU manufacturer, are considered to be downstream users for the only representative, and if necessary they can be recorded in this table-view block of</p>		FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries

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	fields. For each Importer, click the Add row button to create a new row.		
Name	<p>Indicate the name(s) of the other Importer(s), (i.e. the Downstream user(s) under REACH). Click the Link button to select the Supplier and establish the link. If the desired Supplier is not present in your database, click the New button. It will trigger the opening of the Legal entity creation dialogue.</p> <p>The Importer is created and simultaneously linked to the Substance or Mixture dataset. To complete the information of this newly created Legal entity, click the Goto button.</p> <p>The modifications will be automatically updated by clicking the Save button . The Back button button will lead back to section 1.7 Suppliers. The link can be deleted by clicking the Delete button .</p>	Entity reference field	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries.LegalEntity
Agreement	<p>Insert the agreement document. Click the Attachment button and the green Plus button from the context menu appearing. Specify the path and the name of the file to be inserted and indicate any remarks if appropriate</p>	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries.Agreement

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	in the Properties window.		
Other importers			

1.2.1 Location of manufacturing plant(s)

Purpose

Provide the name and address of each manufacturing plant in which the plant protection product and active substance are manufactured.

FLEXIBLE_RECORD.Sites – v.4.0 (Final) [July 2020]			
Name	Instructions	Data Type	Field Path
	<p>Set the confidentiality and regulatory purpose flags. The flag system can be used in case of joint submission of information or if there is more than one manufacturer of the same substance and certain infrastructure/facilities are shared.</p> <p>Caution The flags are set for all sites altogether. There is no possibility to filter out only one Legal entity site from an export file, a print-out or a Dossier.</p> <p>Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants</p>	Confidentiality	FLEXIBLE_RECORD.Sites.DataProtection
Site	<p>Click the green Plus button to open a new repeatable block. An empty block is now ready to be filled in. Add as many</p>	Entity reference field	FLEXIBLE_RECORD.Sites.ReferenceSite

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	<p>repeatable blocks as necessary to list all production and/or /use locations.</p> <p>Site: Click the Link button to select the Site and establish the link. If the desired Site is not present in your database, click the New button. It will trigger the opening of the Legal entity site creation dialogue. The Legal entity site is created and simultaneously linked to the Substance or Mixture dataset. To complete the information of this newly created Site, click the Goto button. The modifications will be automatically updated by clicking the Save button . The Back button will lead back to section 3.3 Sites. The link can be deleted by clicking the Delete button .</p> <p>Caution</p> <p>To delete only the link to the Site information click the Delete button located near the Site field. To delete all information on the Site, click the Delete button located at repeatable block level.</p>		
Remark	A remark field to enter additional information on the Site.	Text area	FLEXIBLE_RECORD.Site s.Remarks

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Manufacture / own use(s)		Header 1	FLEXIBLE_RECORD.Site s.Manufacture
Related manufacture / own use	Click the Linkbutton to select the relates manufacture / own use and establish the link to the Site. Note In case of a Distributor only, no manufacture / own use should be linked to the Site.	Endpoint reference list	FLEXIBLE_RECORD.Site s.Manufacture.Related Manufacture
Related mixture/product		Header 1	FLEXIBLE_RECORD.Site s.RelatedMixtureProduc t
Specify to which mixture/product(s) it applies:		Endpoint reference list	FLEXIBLE_RECORD.Site s.RelatedMixtureProduc t.SpecifyToWhichMixtur eProductSitApplies

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1.3 Producer's development code number if appropriate

Purpose:

Development code numbers of the preparation referred to in the dossier as well as the current names and numbers must be provided.

Full detail of any differences must be provided.

Completion of this document is optional for EU_PPP

FLEXIBLE_RECORD.Identifiers – v.2.3 (Final) [July 2020]			
Name	Instructions	Data Type	Field Path
Regulatory programme identifiers		Header 1	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers
Regulatory programme identifiers			FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers
Flags	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.DataProtection
Regulatory programme	Select one identifier type from the drop-down list. . If none of the pre-defined items applies, select other:. A text field is then activated next to the list field in which you can enter any free text.	Open list	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgramme
ID	Not relevant for EU-PPP Insert the identification number distributed by different regulatory programmes (e.g. the REACH registration number).	Text	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.Id
Remarks	If necessary, provide any additional comments here.	Text area	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers

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			toryProgrammeIdentifiers.Remarks
Regulatory programme identifiers			
Other IT system identifiers		Header 1	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers
Other IT system identifiers			FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers
Flags	Set the confidentiality/regulatory purpose information.	Confidentiality	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers.DataProtection
IT system	Specify the IT System identifier (e.g. IUCLID 4)	Text	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers.ExternalSystemDesignator
ID	Insert the corresponding identification number.	Text	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers.Id
Remarks	If necessary, provide any additional comments here.	Text area	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers.Remarks
Other IT system identifiers			

1.4 Detailed quantitative and qualitative information on the composition of the plant protection product

Purpose

This document covers the data requirements:

Detailed quantitative and qualitative information on the composition of the plant protection product/preparation

Product formulation type and function of component

This document is used to link the active substance dataset (and if relevant the other substance dataset) to the Mixture/product

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FLEXIBLE_RECORD.MixtureComposition – v.6.5 (Final) [August 2020]			
Name	Instructions	Data Type	Field Path
Administrative data		Header 1	FLEXIBLE_RECORD.MixtureComposition.AdministrativeData
	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.MixtureComposition.AdministrativeData.DataProtection
General information		Header 1	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation
Mixture/product name	Name of formulation/preparation reported. In case of multiple formulations more than one document can be completed. Linking to reference substances rather than substances is recommended for the additional documents unless a new component which requires a dataset is included.	Text	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.Name
Trade names			FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.TradeNames
Country		Multi select open list	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.TradeNames.Country
Trade name	Trade name of formulation/preparation reported	Multi-line text	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.TradeNames.TradeName
Trade names			
Brief description	Additional information on the formulation/preparation can be added here	Text	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.Description
Formulation type	Select the formulation type according the international coding system for pesticides from the scroll down list	Multi select open list	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.FormulationType
Components		Header 1	FLEXIBLE_RECORD.MixtureComposition.Components
			FLEXIBLE_RECORD.MixtureComposition

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			n.Components.Components
Component flag	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD .MixtureComposition.Components.Components.DataProtection
Name	<p>Link to a reference substance or substance.</p> <p>Select substance for the active substance/micro-organism and relevant impurities. This creates a dataset for each component of this type.</p> <p>Link to reference substance for other components e.g. safeners, synergists, co-formulants, by-products, culture medium etc.</p>	Entity reference field	FLEXIBLE_RECORD .MixtureComposition.Components.Components.Reference
Function	Indicate the function of the component in the formulation.	Open list	FLEXIBLE_RECORD .MixtureComposition.Components.Components.Function
Typical concentration	<p>Complete the Typical concentration reporting %w/w.</p> <p>For microorganisms, the nominal content of viable material is required and concentration range reporting g/kg (or g/l for liquids).</p> <p>For relevant impurities the range including the maximum content is required.</p> <p>For microorganisms the range - maximum and minimum viable material is required</p> <p>Where relevant, the corresponding content of the variant (such as salts and esters) of the active substances should be included as components.</p>	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD .MixtureComposition.Components.Components.TypicalConcentration
Concentration range	Scientific notation can be used, e.g. $1e-3 = 0.001$ or $1e6 = 1000000$	Range with open list (Decimal)	FLEXIBLE_RECORD .MixtureComposition.Components.Components.ConcentrationRange
Remarks	Additional information on the quantity of each component in the formulation/preparation which cannot be provided in the other fields	Text area	FLEXIBLE_RECORD .MixtureComposition.Components.Components.Remarks
Substance of concern	The additional check boxes in this table are not relevant for European Plant Protection Products	Check box	FLEXIBLE_RECORD .MixtureComposition.Components.Components.SubstanceOfConcern

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Generic component identifier (GCI)		Check box	FLEXIBLE_RECORD.MixtureComposition.Components.Components.Gci
Interchangeable component group (ICG)		Check box	FLEXIBLE_RECORD.MixtureComposition.Components.Components.Icg
Standard formula (SF) component		Check box	FLEXIBLE_RECORD.MixtureComposition.Components.Components.Sfc
Substance generated in situ (from one or more precursors, at the place of use)		Check box	FLEXIBLE_RECORD.MixtureComposition.Components.SubstanceGeneratedInSitu

Links to support material:

[Catalogue of pesticide formulation types and international coding system](#)

1.4.4 Information on metabolites

Purpose:

Any information on potentially harmful effects of metabolites on human and animal health, the environment or on groundwater shall be included in the dossier.

Chemical name in accordance with IUPAC and CA nomenclature, CAS-number EC number, molecular and structural formula, molar mass shall be reported

FLEXIBLE_SUMMARY.Metabolites v1.2 (Final)

Name	Instructions	Data type	Field path
Metabolites information		Header 1	FLEXIBLE_SUMMARY.Metabolites.MetabolitesInfo
Metabolites information overview	<p>Description of the metabolites included in the dossier.</p> <p>For microorganisms in cases where other strains belonging to the same microbial species are known to produce</p>	Rich text area	FLEXIBLE_SUMMARY.Metabolites.MetabolitesInfo.MetabolitesInfoOverview

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	metabolites with unacceptable effects on human health and/or the environment, this should be described here.		
Parent of metabolites	<p>Link to the parent of the metabolites in the 'List of metabolites'.</p> <p>If more than one active substance is included in the dossier mixture composition, then parent of the metabolites must be reported</p> <p>If the metabolite is secondary or tertiary, then the parent of the metabolites must be reported</p> <p>The link should be made to the reference substance of the parent</p>	Entity reference field	FLEXIBLE_SUMMARY.Metabolites.MetabolitesInfo.ParentOfMetabolites
List of metabolites		Header 1	FLEXIBLE_SUMMARY.Metabolites.ListMetabolites
Metabolites	<p>The general rules on confidentiality requests apply in setting the flags (Administrative data summary – common block). See section on Confidentiality of dossiers</p>		FLEXIBLE_SUMMARY.Metabolites.ListMetabolites.Metabolites

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		Confidentiality	FLEXIBLE_SUMMARY.Metabolites.ListMetabolites.Metabolites.DataProtection
Link to metabolite dataset	<p>A metabolite dataset is required where further studies have been performed using a metabolite as the test material. The link must be made using a substance to create a dataset. In the dataset linked to the substance endpoint study records and endpoint summaries can be completed in the relevant sections e.g. Toxicological and metabolism studies, Fate and behaviour in the environment, Ecotoxicological studies. The Table of Contents for a metabolites is the 'Other substance' dataset</p> <p>Where a metabolite is detected and reported in an endpoint study record and the test material is the active substance only a link to a reference substance is required.</p> <p>In both cases the IUPAC and CA nomenclature, CAS-number EC number,</p>	Entity reference field	FLEXIBLE_SUMMARY.Metabolites.ListMetabolites.LinkMetaboliteDataset

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	<p>molecular and structural formula, molar mass should be reported in the reference substance document. SMILES and InChi are recommended.</p> <p>Any metabolites included in this document must be reported in the results of in at least one endpoint study record where the test material is the active substance</p>		
Remarks	<p>Further information on the inclusion of the metabolite in document can be included e.g. 'found in lysimeter studies at annual average concentrations exceed 0.1 µg/L in the leachate' or 'metabolite included in residue definition for environmental monitoring'</p>	Multi-line text	FLEXIBLE_SUMMARY.Metabolites.ListMetabolites.Metabolites.Remarks
Metabolites			
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key 	Header 1	FLEXIBLE_SUMMARY.Metabolites.Discussion

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	<p>value that characterises the endpoint</p> <ul style="list-style-type: none"> - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>		
Attached background material	<p>Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.</p>		FLEXIBLE_SUMMARY.Metabolites.Discussion.AttachedBackgroundMaterial
Attached document	<p>The original file only needs to be attached here if it differs from the non-confidential file uploaded under "Attached (sanitised) documents for publication". If a file is uploaded under this field a confidentiality claim must be submitted</p>	Single file attachment	FLEXIBLE_SUMMARY.Metabolites.Discussion.AttachedBackgroundMaterial.AttachedDocument

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	for each part of the file considered confidential.		
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_SUMMARY.Metabolites.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.	Attachments list	FLEXIBLE_SUMMARY.Metabolites.Discussion.AttachedSanitisedDocsForPublication

Links to support material:

[Scientific Opinion on Evaluation of the Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment](#)

IUCLID ACTIVE SUBSTANCE APPLICATION MANUAL

2 Physical, chemical and technical properties of the plant protection product

Purpose

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details for:

- Appearance
- Flammability (state purity)
- Explosive properties (state purity)
- Oxidizing properties (state purity)

ENDPOINT_SUMMARY.PhysicalChemicalProperties – v.5.0 (Final) [July 2020]

Name	Instructions	Data Type	Field Path
Administrative data	See Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.PhysicalChemicalProperties.AdministrativeDataSummary
Additional information	See Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.PhysicalChemicalProperties.Discussion

2.1 Appearance - Endpoint Summary

Purpose

Provide a description of the colour and of the physical state of the plant protection. Provide a description of both the colour, if any, and the physical state of both the active substance as manufactured and purified active substance.

ENDPOINT_SUMMARY.GeneralInformation – v.7.1 (Final) [July 2020]

Name	Instructions	Data Type	Field Path
Administrative data	See Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.GeneralInformation.AdministrativeDataSummary
	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.GeneralInformation.AdministrativeDataSummary.DataProtection

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Link to relevant study record(s)	Provide here the link to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.	Header 1	ENDPOINT_SUMMARY.GeneralInformation.LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	ENDPOINT_SUMMARY.GeneralInformation.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.GeneralInformation.LinkToRelevantStudyRecord.Results
Description of key information	Provide a description of the colour and of the physical state of the plant protection. Provide a description of both the colour, if any, and the physical state of both the active substance as manufactured and purified active substance. Report the purity and/or the specification of the test material and the guideline and method used	Header 1	ENDPOINT_SUMMARY.GeneralInformation.KeyInformation
		Rich text area	ENDPOINT_SUMMARY.GeneralInformation.KeyInformation.KeyInformation
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment
Physical state at 20°C and 1013 hPa	Indicate state at room temperature and atmospheric pressure	Closed list	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.PhysicalState

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Form		Open list	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.Form
Colour	Indicate colour	Multi select closed list	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.Colour
Colour intensity		Closed list	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.ColourIntensity
Additional information	See Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.GeneralInformation.Discussion

2.1 Appearance - Endpoint study record

Purpose:

For active substances provide a description of both the colour, if any, and the physical state of both the active substance as manufactured and purified active substance.

For plant protection product provide a description of the colour and of the physical state of the plant protection.

ENDPOINT_STUDY_RECORD.GeneralInformation – v.6.3 (Final) [September 2020]			
Name	Instructions	Data Type	Field Type
Administrative data	See Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.AdministrativeData
Materials and methods	See Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.MaterialsAndMethods
Test material	See Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneralInformation.MaterialsAndMethods.TestMaterials
Test material information	See Test material	Entity reference field	ENDPOINT_STUDY_RECORD.GeneralInformation.MaterialsAndMethods.TestMaterials.TestMaterialInformation

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Any other information on materials and methods incl. tables	See Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneralInformation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion
Physical state at 20°C and 1013 hPa	Indicate the physical state of the substance at 20°C and 1013 hPa, i.e. gaseous, liquid or solid. In the case of an aerosol (which means aerosol dispenser or aerosol generator), this field can be left empty. However, the type of aerosol dispenser should be reported in the field "Form". Note: The fields on Test Material Information (TMI) should be completed as far as possible even if the information provided is not derived from a study, but taken from non-experimental information. Create separate records if different physical states need to be reported.	Closed list with remarks	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.SubstancePhysicalState
Form / colour / odour	This repeatable block is for recording the physical form of the substance odour and colour. Odour is not a data requirement under regulation (EC) No 1107/2009, provision of this information is optional.		ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock

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	If the substance can have more than one of these properties, copy this block of fields or create additional records as appropriate.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock.KeyResult
Form	Select the physical form of the substance from the picklist, e.g. solid: particulate/powder, solid: nanomaterial, solid: compact, liquid: viscous, etc. If necessary, add further free text description in the adjacent text field, e.g. for further characterising a viscous liquid or an aerosol. The form selected should match with the physical state entered in field 'Physical state at 20°C and 1013 hPa'. The picklist provided is not exhaustive. It includes both comprehensive terms (e.g. 'solid: particulate/powder' or 'solid: nanomaterial') and more specific terms which should be used if possible (e.g. 'solid: flakes' or 'solid: nanomaterial, low aspect ratio'). If substances or mixtures contained in aerosol	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock.Form

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	<p>dispensers are addressed within a specific regulatory framework (e.g. related to classification and labelling), indicate the type of aerosol dispenser.</p> <p>Refer to the guidance documents of the relevant regulatory framework as to the use of this or other template(s) for specifying the physical state, form and other properties of the submission substance during reasonably expected use.</p> <p>Please note: The field 'Test material form' provided in section 'Materials and methods' may be exceptionally obsolete for this template because details on the physical state and form are normally derived from non-experimental information, i.e. handbooks, SDS etc., or based on a visual inspection of the substance.</p>		
Colour	Describe the colour of the substance at 20°C and 1013 hPa. If other environmental conditions apply, specify them.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock.Substance Colour
Odour	Select the odour of the substance from picklist, e.g. biting, pungent, etc.	Open list	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock.Odour

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Form / colour / odour			
Substance type	Select as appropriate or use 'other:' to describe substance type if not available from picklist.	Open list	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.SubstanceType
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.ApplicantSummaryAndConclusion

2.2 Explosive and oxidising properties

2.2.1 Explosive properties – Endpoint summary

<p>Purpose Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details e.g explosive properties (state purity)</p>
--

ENDPOINT_SUMMARY.Explosiveness – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field Path
Administrative data	Administrative data summary – common block Conclude on the explosive properties of the product/substance/preparation (and state purity)	Header 1	ENDPOINT_SUMMARY.Explosiveness.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Explosiveness.ResultsAndDiscussion

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Explosiveness	Select 'explosive', 'non explosive' or no information	Closed list	ENDPOINT_SUMMARY.Explosiveness.ResultsAndDiscussion.Explosiveness
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Explosiveness.Discussion
Justification for classification or non-classification	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Header 1	ENDPOINT_SUMMARY.Explosiveness.Justification

2.2.1 Explosive properties - Endpoint study record

<p>Purpose Explosivity properties will be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria</p>
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ENDPOINT_STUDY_RECORD.Explosiveness – v.6.4 (Final) [September 2020]			
Name	Instructions	Data type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.Explosiveness.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guideline: Method A.14 Explosive properties (Annex to Regulation (EC) No 440/2008) is relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.MaterialsAndMethods

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Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.Explosiveness.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.Explosiveness.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Explosiveness.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion
Small-scale preliminary tests	If a small-scale preliminary test was conducted (e.g. according to EU Method A.14), report the parameter and results. In field 'Remarks on result' you can indicate any qualitative results or if it was not determinable or measured. Copy this block of fields for specifying the relevant values.		ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.KeyResult
Parameter	Select the parameter measured to which the result value relates.	Open list with remarks	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.Parameter

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Value	Enter a numeric value to specify the result of the test.	Decimal	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.Value
Number of fragments	For thermal sensitivity tests with fragmentation of the test tube, indicate the number of fragments.	Decimal	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.NumberOfFragments
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.RemarksOnResults
Small-scale preliminary tests			
Results of test series for explosives	If a substance has explosive properties or is intended to function as explosive, the quantitative and/or qualitative outcome of the relevant tests should be recorded in this repeatable block of fields, as derived according to the test series indicated in the respective field. In field 'Remarks on result' you can give a qualitative description		ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives

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	of results in addition to or if no numeric value(s) were derived. Copy this block of fields for specifying the relevant values.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.KeyResult
Test series	Select the UN test series to which the result value relates. If the test data were derived by a competent authority, select the corresponding phrase.	Open list with remarks	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.TestSeries
Method	Select UN test method to which the result relates.	Open list	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.Method
Parameter	Select the parameter measured to which the result value relates.	Open list with remarks	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.Parameter
Value	Enter a numeric value to specify the result of the test.	Decimal	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.Value
Result	Report the outcome of the test.	Open list with remarks	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.RemarksOnResults

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	<p>derived;</p> <ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 		
Results of test series for explosives			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.ApplicantSummaryAndConclusion

Links to support material:

United Nations New York and Geneva (2009) Publication ISBN 978-92-1-139135-0.

<https://unece.org/DAM/trans/danger/publi/manual/Rev5/English/ST-SG-AC10-11-Rev5-EN.pdf>

2.2.2 Oxidising properties - Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.

Provide only the most relevant details for oxidising properties (state purity)

ENDPOINT_SUMMARY.OxidisingProperties – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.OxidisingProperties.AdministrativeDataSummary

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	Conclude on the oxidising properties of the product/substance/preparation (and state purity)		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.OxidisingProperties.KeyValueChemicalAssessment
Oxidising properties		Closed list	ENDPOINT_SUMMARY.OxidisingProperties.KeyValueChemicalAssessment.Oxidising
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.OxidisingProperties.Discussion
Justification for classification or non-classification	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Header 1	ENDPOINT_SUMMARY.OxidisingProperties.Justification

2.2.2 Oxidising properties - Endpoint study record

<p>Purpose</p> <p>Oxidising properties will be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies.</p> <p>A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria</p>
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ENDPOINT_STUDY_RECORD.OxidisingProperties – v.7.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.OxidisingProperti

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			es.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Solids: Method A.17 Oxidising properties (solids) (Annex to Regulation (EC) No 440/2008); Liquids: Method A.21 Oxidising properties (liquids) (Annex to Regulation (EC) No 440/2008); Test O.1: Test for oxidizing solids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/; Test O.2: Test for oxidizing liquids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/; Test O.3: Gravimetric test for oxidising solids (UN) (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 6; are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Study design		Header 2	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.StudyDesign

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Contact with	Indicate the chemical with which the test substance was brought in contact. Use separate records for each oxidising or reducing agent tested.	Open list	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.StudyDesign.ContactWith
Duration of test (contact time)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.StudyDesign.DurationOfTest
Details on methods	Enter any details that could be relevant for evaluating this study summary, particularly if no guideline was used. For instance, provide the temperature at which the test was started and indicate whether the test was conducted at temperatures expected during the normal use of the substance.	Text area	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.StudyDesign.DetailsOnMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion
Test results (Oxidising gases)	Indicate the type of the parameter measured, i.e. coefficient of		ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion

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	oxygen equivalency (Ci), and the numeric results. As appropriate, enter remarks in the respective subfield and/or field 'Remarks on result'. Copy this block of fields for more than one parameter as appropriate.		n.TestResultOxidisingGases
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussions.TestResultOxidisingGases.KeyResult
Parameter	Select the parameter, e.g. coefficient of oxygen equivalency (Ci). Additional free text explanation can be given in the supplementary remarks field.	Open list	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussions.TestResultOxidisingGases.Parameter
Result	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussions.TestResultOxidisingGases.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussions.TestResultOxidisingGases.RemarksOnResults

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	<p>reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or</p> <p>- entering any remarks by selecting 'other:'.</p>		
Test results (Oxidising gases)			
Test results (Oxidising liquids)	<p>Depending on the method used, indicate the type of sample tested, e.g. 1:1 sample-to-cellulose ratio, and the parameter measured in the respective subfield, e.g. 'mean pressure rise time'. Provide the mean value measured or a range if reported so, and the unit of measurement. As appropriate, enter remarks in the respective subfield and/or field 'Remarks on result'.</p> <p>Copy this block of fields for more than one parameter as appropriate, i.e. to record the maximum burning rate of both the test mixture and the reference mixture.</p>		<p>ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	<p>Check box</p>	<p>ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.KeyResult</p>

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Sample tested	Select the type of sample tested from drop-down list, e.g. 1:1 sample-to-cellulose ratio. Additional free text explanation can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.SampleTested
Parameter	Select the parameter, e.g. maximum burning rate. Additional free text explanation can be given in the supplementary remarks field.	Open list	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.Parameter
Result	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.RemarksOnResults

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Test results (Oxidising liquids)			
Test results (Oxidising solids)	<p>Depending on the method used, indicate the type of sample tested, e.g. 1:1 sample-to-cellulose ratio, and the parameter measured in the respective subfield, e.g. 'mean pressure rise time'. Provide the mean value measured or a range if reported so, and the unit of measurement. As appropriate, enter remarks in the respective subfield and/or field 'Remarks on result'.</p> <p>Copy this block of fields for more than one parameter as appropriate, i.e. to record the maximum burning rate of both the test mixture and the reference mixture.</p>		ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.KeyResult
Sample tested	<p>Select the type of sample tested from drop-down list, e.g. 1:1 sample-to-cellulose ratio. Additional free text explanation can be given in the supplementary remarks field.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.SampleTested

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Parameter	Select the parameter, e.g. maximum burning rate. Additional free text explanation can be given in the supplementary remarks field.	Open list	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.Parameter
Result	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.RemarksOnResults
Test results (Oxidising solids)			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.ApplicantSummaryAndConclusion

2.3 Flammability and self-heating

2.3.1 Flash point - Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details e.g temperature

ENDPOINT_SUMMARY.FlashPoint v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field Path
Administrative data	Administrative data summary – common block Conclude on the flashpoint of the product/substance/preparation (and state purity)	Header 1	ENDPOINT_SUMMARY.FlashPoint.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.FlashPoint.KeyValueForChemicalSafetyAssessment
Flash point at 101 325 Pa	Enter the temperature for flashpoint	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.FlashPoint.KeyValueForChemicalSafetyAssessment.FlashPoint
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.FlashPoint.Discussion

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2.3.1 Flash point - Endpoint study record

Purpose

Flash point must be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

“The flash point of active substances as manufactured with a melting point below 40 °C shall be determined and reported. In justified cases, data for purified active substance may be used.”

The flash point of liquids which contain flammable solvents shall be determined and reported. The flammability of solid plant protection products and gases shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations’ Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria.

ENDPOINT_STUDY_RECORD.FlashPoint – v.7.3 (Final) [September 2020]			
Name	Instructions	Data type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.FlashPoint.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Method A.9 Flash-point (Annex to Regulation (EC) No 440/2008) Test methods according to table 2.6.3 of Annex I, Part 2 of Regulation (EC) No 1272/2008 (liquids) are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods
Flash point apparatus	Indicate the apparatus used for determining the flash point.	Open list with remarks	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.FlashPointApparatus
Dynamic viscosity of test material	For viscous liquids, report the dynamic viscosity of the test material at 20°C (mPa	Multi-line text	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.Dynamic

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	s) and verify that the method chosen is valid according to the criteria given in the relevant test guideline.		cViscosityOfTestMaterial
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion
Flash point	Enter mean flash point or range if reported so, normally determined at 1013 hPa. If necessary, copy this block of fields for each pressure condition at which the flash point was determined.		ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.FlashPoint
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.FlashPoint.KeyResult
Flash point	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.FlashPoint.FPoint

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	use both numeric fields together with the appropriate qualifier(s) if applicable.		
Atm. press.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.FlashPoint.Result.sAndDiscussion.FlashPoint.AtmosphericPressure
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.FlashPoint.Result.sAndDiscussion.FlashPoint.RemarksOnResults
Flash point			
Sustaining combustibility	If a sustaining combustibility test was conducted, specify the test procedure used and report the test result. If necessary, copy this block of fields for test run.		ENDPOINT_STUDY_RECORD.FlashPoint.Result.sAndDiscussion.SustainingCombustibility
Key result	Set this flag for identifying the key information which is of	Check box	ENDPOINT_STUDY_RECORD.FlashPoint.Result.sAndDiscussion.Sustaining

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	potential relevance for hazard/risk assessment or classification purpose.		ngCombustibility.KeyResult
Test procedure	Specify the test procedure used.	Open list with remarks	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.SustainingCombustibility.TestProcedure
Result	This field can be used for: - giving a qualitative description of results - indicating why no result could be determined, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.SustainingCombustibility.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.SustainingCombustibility.RemarksOnResults
Sustaining combustibility			

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Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.FlashPoint.Result sAndDiscussion.AnyOtherInformationOnResults InclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.ApplicantSummaryAndConclusion

Links to support material

United Nations New York and Geneva (2009) Publication ISBN 978-92-1-139135-0.

<https://unece.org/DAM/trans/danger/publi/manual/Rev5/English/ST-SG-AC10-11-Rev5-EN.pdf>

2.3.2 Flammability - Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.

Provide only the most relevant details for flammability (state purity)

ENDPOINT_SUMMARY.Flammability – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block Conclude on the flammability of the product/substance/preparation (and state purity)	Header 1	ENDPOINT_SUMMARY.Flammability.AdministrativeDataSummary
Flammability	Indicate 'flammable', 'pyrophoric', 'substances and mixtures which in contact with water emit flammable gases', 'not classified'	Closed list	ENDPOINT_SUMMARY.Flammability.KeyValueChemicalAssessment.Flammability
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Flammability.Discussion

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2.3.2 Flammability - Endpoint study record

<p>Purpose Flammability must be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies. “The flammability of active substances as manufactured shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations’ Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria (6). In justified cases, data for purified active substance may be used.” The flammability of solid plant protection products and gases shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations’ Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria.</p>

ENDPOINT_STUDY_RECORD.Flammability – v.6.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Flammability.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Flammability.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.Flammability.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Methods A.10 Flammability (solids), A.11 Flammability (gases), A.12 Flammability (contact with water) (Annex to Regulation (EC) No 440/2008) Test N.1: test method for readily combustible solids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/ are relevant for this endpoint)	Header 1	ENDPOINT_STUDY_RECORD.Flammability.MaterialsAndMethods

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Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.Flammability.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.Flammability.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables – (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Flammability.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion
Flammable gases (Lower and upper explosion limit)	<p>Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'.</p> <p>If a gas was tested for flammability, report the lower and upper explosion limit, sometimes also referred to as lower and upper flammability limit. If a calculation method was used fill in the results as far as possible.</p> <p>In field 'Remarks on result' you can indicate if no flammability occurred (no flammable</p>		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit

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	range with air at 20°C and a standard pressure of 101.3 kPa) or if it was not determinable or measured. Copy this block of fields for specifying the relevant values.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit.Key Result
Parameter	Select the parameter from drop-down list, i.e. lower explosion limit or upper explosion limit.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit.Parameter
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit.Value
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit.RemarksOnResults

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	entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.		
Flammable gases (Lower and upper explosion limit)			
Aerosols	<p>Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'.</p> <p>If an aerosol (which means an aerosol dispenser) was tested for flammability, indicate the type of aerosol tested, the respective test parameter and the result.</p> <p>In field 'Remarks on result' you can indicate for instance if no ignition occurred or if it was not determinable or measured.</p> <p>Copy this block of fields for specifying the relevant values.</p>		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.KeyResult

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	or classification purpose.		
Type of aerosol tested	Indicate the type of aerosol dispenser tested, i.e. 'aerosol dispenser: foam aerosol' or 'aerosol dispenser: spray aerosol'. Select 'aerosol dispenser: not specified' if the type is not specified. Specific test parameters apply depending on the aerosol type.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.TypeOfAerosolTested
Content of flammable components (%)	Specify the content of flammable components in %. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.ContentOfFlammableComponents
Test parameter	Select the parameter from drop-down list.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.TestParameter
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.Value

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Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_STUDY_RESULT_AND_DISCUSSION.AEROSOLS.REMARKS_ON_RESULTS
Aerosols			
Flammable solids	<p>Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'.</p> <p>If a solid was tested for flammability, report the test procedure used and the measured burning time.</p> <p>In field 'Remarks on result' you can indicate if no flammability occurred or if it was not determinable or measured.</p> <p>Copy this block of fields for specifying the relevant values.</p>		ENDPOINT_STUDY_RESULT_AND_DISCUSSION.FLAMMABLE_SOLID

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Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids.KeyResult
Test procedure	Select the parameter from drop-down list, i.e. burning rate test: preliminary screening test, burning rate test over 100 mm length, burning rate test with wetted zone, burning time over 250 mm for metal powders or metal alloys.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids.TestProcedure
Burning time	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids.BurningTime
Moisture (wt %)	Enter a numeric value to specify the moisture as wt %.	Decimal	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids.MoistureWt
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids.RemarksOnResults

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	entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.		
Flammable solids			
Pyrophoric solids	Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'. If a pyrophoric solid was tested for flammability, report the test procedure used and the measured result, i.e. ignition time on contact with air. In field 'Remarks on result' you can indicate if no ignition occurred or if it was not determinable or measured. Copy this block of fields for specifying the relevant values.		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.KeyResult
Test procedure	Select the parameter from drop-down list,	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Pyro

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	i.e. ignition time on contact with air.		phoricSolids.TestProcedure
Result	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.Results
Temp.	Enter a numeric value to specify the air temperature.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.Temp
Relative air humidity (%)	Enter a numeric value to specify the relative air humidity in %.	Decimal	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.RelativeAirHumidity
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.RemarksOnResults
Pyrophoric solids			
Pyrophoric liquids	Depending on the information requirement addressed in field 'Endpoint' the		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids

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	<p>respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'.</p> <p>If a pyrophoric liquid was tested for flammability, report the test procedure used and the measured result, i.e. ignition time on contact with air. In field 'Remarks on result' you can indicate if no ignition occurred or if it was not determinable or measured.</p> <p>Copy this block of fields for specifying the relevant values.</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.KeyResult
Test procedure	<p>Select the parameter from drop-down list, i.e. ignition time on contact with air or effect on filter paper.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.TestProcedure
Result	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields</p>	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.Results

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	together with the appropriate qualifier(s) if applicable.		
Temp.	Enter a numeric value to specify the air temperature.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.Temp
Relative air humidity (%)	Enter a numeric value to specify the relative air humidity in %.	Decimal	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.RelativeAirHumidity
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.RemarksOnResults
Pyrophoric liquids			
Self-heating substances / mixtures	Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'. If a self-heating substance / mixture		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures

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	was tested for oxidative self-heating, report the test procedure used and the result. Copy this block of fields for specifying the relevant values for each test procedure used.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures.KeyResult
Test procedure	Select the parameter from drop-down list, i.e. 25 mm sample cube at 140°C, 100 mm sample cube at 140°C, 100 mm sample cube at 120°C or 100 mm sample cube at 100°C.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures.TestProcedure
Max. temp. reached	Enter a numeric value to specify the maximum temperature reached.	Decimal	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures.MaxTempReached
Induction time (h)	Enter a numeric value to specify the induction time.	Decimal	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures.InductionTimeH
Result	Report the outcome of test using the test criteria and method of assessing results of the relevant (e.g. UN) test method.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived;	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures.RemarksOnResults

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	<ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 		
Self-heating substances / mixtures			
Substances / mixtures which in contact with water emit flammable gases	<p>Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'.</p> <p>If a substance / mixture was tested for release of flammable gas, report the test procedure, i.e. step according to the test guideline (i.e. UN Test N.5) and the maximum release rate.</p> <p>In field 'Remarks on result' you can indicate if no ignition occurred or if it was not determinable or measured.</p> <p>Copy this block of fields for specifying the relevant values.</p> <p>In field 'Remarks on</p>		<p>ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases</p>

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	<p>result' you can indicate if no ignition occurred or if it was not determinable or measured. Copy this block of fields for specifying the relevant values.</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.KeyResult
Test procedure	<p>Select the step(s) of the test procedure from the multiple drop-down list.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.TestProcedure
Max. rate of gas release	<p>Enter a numeric value to specify the maximum rate of gas release.</p>	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.MaxRateOfGasRelease
Identity of evolved gas	<p>If gas evolved specify the identity or, if not known, select 'unknown'.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.IdentityOfEvolvedGas
Remarks on result	<p>This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g.</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.RemarksOnResults

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	by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.		
Substances / mixtures which in contact with water emit flammable gases			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Flammability.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Flammability.ApplicantSummaryAndConclusion

Links to support material

United Nations New York and Geneva (2009) Publication ISBN 978-92-1-139135-0.

<https://unece.org/DAM/trans/danger/emark/manual/Rev5/English/ST-SG-AC10-11-Rev5-EN.pdf>

2.3.3 Self-heating - Endpoint summary

Purpose

Summary of the most of the relevant study(-ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details e.g. state purity.

ENDPOINT_SUMMARY.AutoFlammability – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field Path
Administrative data	Administrative data summary – common block Conclude on the self-heating properties of	Header 1	ENDPOINT_SUMMARY.AutoFlammability.AdministrativeDataSummary

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	the product/substance/preparation (and state purity)		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.AutoFlammability.KeyValueForChemicalSafetyAssessment
Autoflammability / Self-ignition temperature at 101 325 Pa		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.AutoFlammability.KeyValueForChemicalSafetyAssessment.AutoFlammability
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AutoFlammability.Discussion

2.3.3 Self-heating - Endpoint study record

<p>Purpose</p> <p>The self-heating shall be determined and reported, unless it can be justified that it is technically or scientifically not necessary to perform such studies</p> <p>The self-heating of active substances as manufactured shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria. In justified cases, data for purified active substance may be used.</p>
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ENDPOINT_STUDY_RECORD.AutoFlammability – v.6.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.AutoFlammability.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Methods A.15 Auto-ignition temperature	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.MaterialsAndMethods

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	(liquids and gases), A16 Relative self-ignition temperature for solids, (Annex to Regulation (EC) No 440/2008) Test N.4: test method for self-heating substances (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/ are relevant for this endpoint		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AutoFlammability.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.AutoFlammability.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables – (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AutoFlammability.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion
Auto-ignition temperature (liquids / gases)	Enter the auto-ignition temperature for liquids or gases, i.e. the lowest temperature at which the test substance will ignite in contact with air under the conditions defined in the test method. Also indicate the atmospheric pressure at which it was determined in the respective subfield. If necessary, copy this		ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability

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	block of fields for each condition.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability.KeyResult
Auto-ignition temperature	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability.Flammability
Atm. Press.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability.AtmosPressure
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text	Open list with 99emark (2000)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability.RemarksOnResults

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	<p>explanation in the supplementary remarks field; or</p> <ul style="list-style-type: none"> - entering any remarks by selecting 'other:'. 		
Auto-ignition temperature (liquids / gases)			
Relative self-ignition temperature (solids)	<p>Enter the relative self-ignition temperature for solids, i.e. the minimum ambient temperature at which a certain volume of a substance will ignite under defined conditions. If necessary, copy this block of fields for each condition.</p>		<p>ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.RelativeSelfIgnitionTemperatureSolids</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	<p>Check box</p>	<p>ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.RelativeSelfIgnitionTemperatureSolids.KeyResult</p>
Relative self-ignition temperature	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	<p>Range with closed list (Decimal)</p>	<p>ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.RelativeSelfIgnitionTemperatureSolids.RelativeSelfIgnitionTemperature</p>
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined 	<p>Open list with 100emark (2000)</p>	<p>ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.RelativeSelfIgnitionTemperatureSolids.RemarksOnResults</p>

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	reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.		
Relative self-ignition temperature (solids)			
Self-ignition temperature of dust accumulation	Enter the self-ignition temperature for a dust, i.e. the lowest temperature, at which under specified test conditions a dust accumulation under the influence of high temperature in the surroundings will just be ignited by self-heating. The self-ignition temperature of a dust accumulation depends on the volume and the shape of the dust sample. Therefore the field 'Volume / surface ratio (m)' should be completed as well. If necessary, copy this block of fields for each condition.		ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperatureOfDustAccumulation
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperatureOfDustAccumulation.KeyResult
Self-ignition temperature	Enter a single numeric value in the first numeric field if you select no qualifier or	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperature

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	'>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		eOfDustAccumulation.SelfIgnitionTemperature
Volume / surface ratio (m)	Enter a numeric value to specify the volume / surface ratio (unit: m).	Decimal	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperatureOfDustAccumulation.VolumeSurfaceRatioM
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with 102emark (2000)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperatureOfDustAccumulation.RemarksOnResults
Self-ignition temperature of dust accumulation			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.ApplicantSummaryAndConclusion
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Links to supporting material

United Nations New York and Geneva (2009) Publication ISBN 978-92-1-139135-0.

<https://unece.org/DAM/trans/danger/publi/manual/Rev5/English/ST-SG-AC10-11-Rev5-EN.pdf>

2.4 Acidity/alkalinity and pH value - Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.

Provide only the most relevant details e.g. state purity, pH

ENDPOINT_SUMMARY.pH – v.4.1 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block Conclude on the pH of the product/substance/preparation	Header 1	ENDPOINT_SUMMARY.pH.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment
pH is not relevant		Check box	ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment.pHNotRelevant
Justification		Closed list	ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment.Justification
pH value		Range (Decimal)	ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment.pH
Solution concentration (%)		Decimal	ENDPOINT_SUMMARY.pH.KeyValueForChemicalSafetyAssessment.SolutionConcentration
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.pH.Discussion

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2.4 Acidity/alkalinity and pH value - Endpoint study record

Purpose

Acidity, alkalinity and pH will be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies

In the case of aqueous plant protection products, the pH value of the neat plant protection product shall be determined and reported.

In the case of solid and non-aqueous liquid plant protection products which are to be applied as aqueous dilutions the pH of a 1 % dilution of the plant protection product shall be determined and reported.

In the case of plant protection products which are acidic (pH < 4) or alkaline (pH > 10) the acidity or alkalinity shall be determined and reported.

ENDPOINT_STUDY_RECORD.pH – v.7.3 (Final) [September 2020]

Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Ph.Administrative Data
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Ph.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.Ph.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.Ph.MaterialsAnd Methods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.Ph.MaterialsAnd Methods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.Ph.MaterialsAnd Methods.TestMaterials.TestMaterialInformation
Reagents		Header 2	ENDPOINT_STUDY_RECORD.Ph.MaterialsAnd Methods.Reagents
Reagent	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.Ph.MaterialsAnd Methods.Reagents.Reagent
Titration of acidity and alkalinity		Header 2	ENDPOINT_STUDY_RECORD.Ph.MaterialsAnd Methods.TitrationOfAcidityAndAlkalinity

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Details on titrant used	Use free text template and delete/add elements as appropriate. Enter any details that could be relevant. Note that any information that can be claimed confidential should be included in the subsequent field 'Confidential details on test material'. Explanations: - Volume of titrant used is usually expressed in mL	Text template	ENDPOINT_STUDY_RECORD.Ph.MaterialsAndMethods.TitrationOfAcidityAndAlkalinity.DetailsOnTitrantUsed
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Ph.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion
pH value	Enter mean pH value or range if reported so and indicate the temperature and concentration at which the pH was determined. If necessary, copy this block of fields for different conditions		ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.pHValue
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.pHValue.KeyResult
pH value	Enter a single numeric value in the first numeric field if you select no qualifier or	Range (Decimal)	ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.pHValue.Value

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	'>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
Temp.	Enter a numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.pHValue.Temp
Concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.pHValue.Concentration
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.pHValue.RemarksOnResults
pH value			
Acidity or alkalinity	Enter the information on acidity or alkalinity. If necessary, copy this		ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.AcidityOrAlkalinity

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	block of fields for different conditions.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RE CORD.Ph.ResultsAndDis cussion.AcidityOrAlkalini ty.KeyResult
Acidity or alkalinity	Enter a numeric value or a range of numeric values according to following conventions: (i) In the first numeric field, enter a single value (Qualifier subfield left blank) or a value if preceded by '>', '>=' or 'ca.' (e.g. '2', 'ca. 2', '>2'). (ii) In the second numeric field, enter a single value if preceded by '<' or '<='. (iii) Use both numeric fields and, as required, the lower and upper qualifier field to enter a range of numeric values (e.g. '2 - 8' or '>2 <8'). Please note: These are examples only. Allowed values are defined for each numeric field.	Closed list	ENDPOINT_STUDY_RE CORD.Ph.ResultsAndDis cussion.AcidityOrAlkalini ty.AcidityOrAlkalinity
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RE CORD.Ph.ResultsAndDis cussion.AcidityOrAlkalini ty.Value

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Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RE CORD.Ph.ResultsAndDis cussion.AcidityOrAlkalini ty.RemarksOnResults
Acidity or alkalinity			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RE CORD.Ph.ResultsAndDis cussion.AnyOtherInfor mationOnResultsInclTa bles
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RE CORD.Ph.OverallRemar ksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RE CORD.Ph.ApplicantSum maryAndConclusion

2.5 Viscosity and surface tension

2.5.1 Viscosity - Endpoint summary

<p>Purpose Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details e.g. viscosity</p>

ENDPOINT_SUMMARY.Viscosity – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY. Viscosity.Administrative DataSummary

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	Conclude on the viscosity of the product/substance/preparation		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Viscosity.KeyValueForChemicalSafetyAssessment
Viscosity		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Viscosity.KeyValueForChemicalSafetyAssessment.Viscosity
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Viscosity.KeyValueForChemicalSafetyAssessment.AtTheTemperatureOf
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Viscosity.Discussion

2.5.1 Viscosity - Endpoint study record

<p>Purpose</p> <p>Viscosity will be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies.</p> <p>For liquid formulations the viscosity shall be determined at two shear rates and at 20°C and 40°C and reported together with the test conditions.</p>
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ENDPOINT_STUDY_RECORD.Viscosity – v.7.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Viscosity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Viscosity.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.Viscosity.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.Viscosity.MaterialsAndMethods
Standard covering the apparatus used	Indicate the standard which covers apparatus used in the method	Text area	ENDPOINT_STUDY_RECORD.Viscosity.MaterialsAndMethods.Standard

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	(ISO, DIN, DIN ISO, ASTM, CIPAC, national standard or other). A list of such possible standards is provided in the OECD Guideline 114, section 'Description of the Method – Apparatus'.		CoveringTheApparatus Used
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.Viscosity.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.Viscosity.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Viscosity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Viscosity	If applicable, enter mean viscosity value or range if reported so and indicate the temperature at measurement in the respective subfield. If necessary, copy this block of fields for each temperature. Note specific to viscosity of liquids: For non-Newtonian fluids the results obtained are preferred in table or graph form, in the order of increasing shear rates. Include table in the rich text field 'Any other information on results incl. tables'. Upload image file in field		ENDPOINT_STUDY_RECORD.Viscosity.ResultsAndDiscussion.Viscosity

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	'Illustration (picture/graph)'. Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Viscosity.ResultsAndDiscussion.Viscosity.KeyResult
Temp.	Select the appropriate value of temperature. If not available from the picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.Viscosity.ResultsAndDiscussion.Viscosity.Temp
Parameter	Indicate the parameter measured.	Open list	ENDPOINT_STUDY_RECORD.Viscosity.ResultsAndDiscussion.Viscosity.Parameter
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.Viscosity.ResultsAndDiscussion.Viscosity.Viscosity
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Viscosity.ResultsAndDiscussion.Viscosity.RemarksOnResults

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	- entering any remarks by selecting 'other:'.		
Viscosity			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Viscosity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Viscosity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Viscosity.ApplicantSummaryAndConclusion

2.5.2 Surface tension - Endpoint summary

<p>Purpose Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details e.g. Surface tension</p>

ENDPOINT_SUMMARY.SurfaceTension – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block Conclude on the surface tension of the product/substance/preparation (state concentration, temperature and purity)	Header 1	ENDPOINT_SUMMARY.SurfaceTension.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.SurfaceTension.KeyValueForChemicalSafetyAssessment
Surface tension		Decimal	ENDPOINT_SUMMARY.SurfaceTension.KeyValueForChemicalSafetyAssessment.SurfaceTension

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in mN/m at 20°C and concentration in mg/L		Decimal	ENDPOINT_SUMMARY.SurfaceTension.KeyValueForChemicalSafetyAssessment.Concentration
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.SurfaceTension.Discussion

2.5.2 Surface tension - Endpoint study record

Purpose

Surface tension will be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

For liquid formulations the viscosity shall be determined at two shear rates and at 20°C and 40°C and reported together with the test conditions. The surface tension shall be determined at the highest concentration.

For liquid plant protection products containing ≥ 10 % hydrocarbons and for which the kinematic viscosity is less than 7×10^{-6} m²/sec at 40 °C the surface tension of the neat formulation shall be determined at 25 °C and reported.

ENDPOINT_STUDY_RECORD.SurfaceTension – v.6.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.SurfaceTension.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Method A.5 Surface tension (Annex to Regulation (EC) No 440/2008) OECD Test Guideline 115: Surface tension of aqueous solutions are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods

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Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Study design		Header 2	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods.StudyDesign
Details on methods	Enter any details that could be relevant for evaluating this study summary. Use freetext template as appropriate.	Text template	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods.StudyDesign.DetailsOnMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion
Surface tension	Enter mean surface tension or range if reported so and indicate the temperature and test substance concentration in the respective subfields. If necessary, copy this block of fields.		ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension.KeyResult

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Surface tension	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension.Tension
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension.Temp
Conc.	Enter numeric value and unit.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension.Conc
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension.RemarksOnResults
Surface tension			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.ApplicantSummaryAndConclusion

2.6 Relative density and bulk density – Endpoint summary

<p>Purpose: Summary information of to the most relevant study(ies) for relative or bulk (pour and tap) density from which the key value is derived.</p> <p>Enter a short description of the most relevant endpoint data. The short description could include for example:</p> <ul style="list-style-type: none"> - the test guideline used, - type of method or reference to the standard or the test method applied. - test material purity and specification - relative density value (for liquid plant protection products) - bulk density (pour and tap) of plant protection products which are powders or granules

ENDPOINT_SUMMARY.PcDensity v.5.0 (Final) [July 2020]			
Name	Instructions	Data Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.PcDensity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.PcDensity.KeyValueForChemicalSafetyAssessment
Relative density at 20C		Decimal	ENDPOINT_SUMMARY.PcDensity.KeyValueForChemicalSafetyAssessment.RelativeDensity
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.PcDensity.Discussion

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2.6 Relative density and bulk density – Endpoint study record

Purpose:

The relative density of liquid plant protection products or the bulk density (pour and tap) of plant protection products which are powders or granules shall be determined and reported.

The density (ρ) of a substance is the quotient of the mass m and its volume V : $\rho = m/V$ SI units (kg/m³).

The relative density D_{20/4} of solids or liquids is the ratio between the mass of a volume of substance to be examined, determined at 20°C, and the mass of the same volume of water, determined at 4°C.

The relative density is dimensionless.

The tests have to be run at 20°C, and at least two measurements performed.

ENDPOINT_STUDY_RECORD.Density v.6.3 (Final) [September 2020]				
Name	Instructions	Data Type	Field path	Containing Block name
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Density.AdministrativeData	Administrative data record block
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Density.DataSource	Data source block (Literature Reference)
Materials and methods	<p>Material and methods – common block</p> <p>Applicable test methods and guidelines: Relative density: Method A.3 Relative density (Annex of Regulation (EC) No 440/2008). or OECD Test Guideline 109</p> <p>Bulk density: CIPAC method MT 186: Bulk density</p> <p>The following test methods can be used:</p> <ul style="list-style-type: none"> - Hydrometer (liquids), - Hydrostatic balance (solids/liquids), - Immersion ball (liquids), - Pycnometer (solids/liquids), - Air comparison pycnometer (solids), 	Header 1	ENDPOINT_STUDY_RECORD.Density.MaterialsAndMethods	

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Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Density.MaterialsAndMethods.TestMaterials	Test materials block
Dynamic viscosity of test material	For viscous liquids, report the dynamic viscosity of the test material at 20°C (mPa s) and verify that the method chosen is valid according to the criteria given in the relevant test guideline.	Multi-line text	ENDPOINT_STUDY_RECORD.Density.MaterialsAndMethods.TestMaterials.DynamicViscosityOfTestMaterial	
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Density.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables	Any other information on materials and methods incl. tables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Density.ResultsAndDiscussion	
Density	Select type of density, e.g. bulk density (in kg/m ³ ; for solids only), density in g/cm ³ or dimensionless relative density (related to water at 4 °C) and enter mean value or range if reported so. For relative density, leave subfield 'Unit' empty. If another water temperature than 4 °C applies or if another reference material was used, select 'other:' in subfield 'Unit' and specify accordingly. Also provide the temperature at which the density of the test material was determined. For comparison reason, the data should be recorded in degrees Celsius (°C). If reported in degrees Fahrenheit (°F), it is recommended to convert to °C. By copying this block of fields both the the original and converted value(s) can be entered.		ENDPOINT_STUDY_RECORD.Density.ResultsAndDiscussion.Density	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.Density.ResultsAndDiscussion.Density.KeyResult	
Type	Select from drop-down list.	Open list with remarks	ENDPOINT_STUDY_RECORD.Density.ResultsAndDiscussion.Density.Type	
Density	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='.	Range with open list	ENDPOINT_STUDY_RECORD.Density.ResultsAndDiscussion.Density.Density	

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	For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	(Decimal)		
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Density.ResultsAndDiscussion.Density.Temp	
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Density.ResultsAndDiscussion.Density.RemarksOnResults	
Density				
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Density.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables	Any other information on results incl. tables Block
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Density.OverallRemarksAttachments	Overall remarks, attachments block
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Density.ApplicantSummaryAndConclusion	Applicant's summary and conclusion block

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2.7 Storage stability and shelf-life, effects of temperature on technical characteristics of the product

2.7.1 Storage stability tests - Endpoint summary

Purpose

The physical and biological stability of the preparation at the recommended storage temperature including information on the growth of contaminating micro-organisms must be determined and reported. The conditions under which the test has been performed must be justified.

The shelf life of the preparation at the recommended storage temperature must be reported. Where shelf life is less than two years, the shelf life in months, with appropriate temperature specifications, must be reported. Useful information is given in GIFAP Monograph No 17.

The stability of the plant protection product after accelerated storage for 14 days at 54 °C shall be determined and reported. Data generated from alternative time/temperature combinations (for example 8 weeks at 40 °C, 12 weeks at 35 °C or 18 weeks at 30 °C) may be submitted as alternative accelerated storage data. Consideration shall be given to performing this test in packaging made of the same material as the commercial packaging.

If the active substance content after the heat stability test has decreased by more than 5 % from the initial value, then information on the breakdown products shall be supplied.

For liquid plant protection products, the effect of low temperatures on stability shall be determined and reported.

The shelf life of the plant protection product at ambient temperature shall be determined and reported. Where shelf life is less than two years, the shelf life in months, with appropriate temperature specifications, shall be reported. The ambient temperature stability test shall be performed in packaging made of the same material as the commercial packaging. Where appropriate, data on the content of relevant impurities, before and after storage, shall be provided.

ENDPOINT_SUMMARY.StorageStability – v.5.0 (Final) [July 2020]

Name	Instructions	Data Type	Field Path
Administrative data	Administrative data summary – common block Conclude on the shelf life and storage stability of the product/preparation	Header 1	ENDPOINT_SUMMARY.StorageStability.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.StorageStability.Discussion

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2.7.1 Storage stability tests - Endpoint study record

Purpose Effect of exposure to air, packaging, etc., on the product stability must be explored.			
ENDPOINT_STUDY_RECORD.StorageStability – v.7.3 (Final) [September 2020]			
Name	Instructions	Data Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.StorageStability.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.StorageStability.DataSource
Materials and methods	Material and methods – common block Applicable test guidelines: Technical Monograph 17 Guidelines for Specifying the Shelf Life of Plant Protection Products and OECD: GUIDANCE DOCUMENT ON STORAGE STABILITY OF MICROBIAL PEST CONTROL PRODUCTS, Series on Pesticides, No. 85 are relevant for microorganisms	Header 1	ENDPOINT_STUDY_RECORD.StorageStability.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.StorageStability.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.StorageStability.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Study design		Header 2	ENDPOINT_STUDY_RECORD.StorageStability.MaterialsAndMethods.StudyDesign
Type of container material	Indicate the overall results with regard to	Open list with remarks	ENDPOINT_STUDY_RECORD.StorageStability.

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	<p>storage stability or reactivity towards container material. Multiple selection is possible. If not listed, select 'other' and specify. Any additional information can be provided in the supplementary remarks text.</p>		MaterialsAndMethods.StudyDesign.ContainerMaterial
Details on study design	<p>Using the freetext template (delete/add elements as appropriate) describe the test procedure and conditions. If the test product is to be supplied in different packaging, test results for each type should be provided (possibly in separate records if appropriate). Explanations: - PACKAGING: Describe the type of container (e.g. can, spray, bottle, sachet, etc.) used in the study, the pack size and approximate empty weight or volume. - TEST CONDITIONS: Report the study duration, the time at sampling, temperature and humidity recorded at regular intervals (e.g. average monthly values or monthly maximum/minimum values). Add any other relevant parameters as appropriate. - ANALYTICAL METHODS: If the active</p>	Text template	ENDPOINT_STUDY_RECORD.StorageStability.MaterialsAndMethods.StudyDesign.DetailsOnStudyDesign

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	<p>ingredient was analysed in storage stability studies, describe the method used and/or refer to the record in the submission where the validated analytical method of the active ingredient is described. Also note any relevant handling of test samples prior to sampling (e.g. shaking).</p> <p>- OTHER: Include any other relevant information.</p>		
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p>	Header 2	ENDPOINT_STUDY_RECORD.StorageStability.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.StorageStability.ResultsAndDiscussion
Results	<p>Briefly summarise relevant observations test results. Use freetext template and delete/add elements as appropriate depending on the type of study. Where appropriate include table(s) in the rich text field 'Any other information on results incl. tables'. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>As appropriate also attach any figures in</p>	Text template	ENDPOINT_STUDY_RECORD.StorageStability.ResultsAndDiscussion.Results

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	field 'Attached background material'.		
Transformation products	Transformation products BLOCK (OHT) Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RE CORD.StorageStability. ResultsAndDiscussion.T ransformationProducts
Storage stability / reactivity towards container material	Indicate the overall results with regard to storage stability or reactivity towards container material. If not listed select 'other:' and specify. Any additional information can be provided in the supplementary remarks text. Multiple selection is possible.	Multi select open list with remarks	ENDPOINT_STUDY_RE CORD.StorageStability. ResultsAndDiscussion.C ontainerMaterial
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RE CORD.StorageStability. ResultsAndDiscussion.A nyOtherInformationOnR esultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RE CORD.StorageStability. OverallRemarksAttachm ents
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RE CORD.StorageStability. ApplicantSummaryAndC onclusion

Links to support material:

OECD GUIDANCE DOCUMENT ON STORAGE STABILITY OF MICROBIAL PEST CONTROL PRODUCTS
[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2016\)54&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)54&doclanguage=en)
 Technical Monograph n°17 Guidelines for Specifying the Shelf Life of Plant Protection Products
<https://croplife.org/wp-content/uploads/2014/05/Technical-Monograph-17-2nd-edition-June-2009.pdf>

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2.7.2 Effects of temperature on technical characteristics of the product - Endpoint summary

<p>Purpose Summary information of the effects of light, temperature, and humidity. Effect of low temperatures on physical stability for liquid preparations</p>
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ENDPOINT_SUMMARY.StabilityThermal – v.5.0 (Final) [July 2020]			
Name	Instructions	Data Type	Field Path
Administrative data	Administrative data summary – common block Conclude on the thermal stability of the product/preparation	Header 1	ENDPOINT_SUMMARY.StabilityThermal.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.StabilityThermal.Discussion
Justification for classification or non-classification	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Header 1	ENDPOINT_SUMMARY.StabilityThermal.Justification

2.7.2 Effects of temperature on technical characteristics of the product - Endpoint study record

<p>Purpose In the case of liquid preparations, the effect of low temperatures on physical stability, must be determined and reported in accordance with CIPAC Methods MT 39, MT 48, MT 51 or MT 54 as appropriate.</p>

ENDPOINT_STUDY_RECORD.StabilityThermal – v.6.4 (Final) [October 2020]			
Name	Instructions	Data Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityThermal.AdministrativeData
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityThermal.DataSource

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Materials and methods	Material and methods – common block Note: CIPAC Methods MT 39, MT 48, MT 51 or MT 54 are relevant for this endpoint for microorganisms	Header 1	ENDPOINT_STUDY_RE CORD.StabilityThermal. MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RE CORD.StabilityThermal. MaterialsAndMethods.T estMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RE CORD.StabilityThermal. MaterialsAndMethods.T estMaterials.TestMateri alInformation
Specific details on test material used for the study			
Specific details on test material used for the study (confidential)			
Study design		Header 2	ENDPOINT_STUDY_RE CORD.StabilityThermal. MaterialsAndMethods.St udyDesign
Details on methods	Enter any details that could be relevant for evaluating this study summary, particularly if no guideline was used. For example, the packaging materials used in the storage stability testing.	Text area	ENDPOINT_STUDY_RE CORD.StabilityThermal. MaterialsAndMethods.St udyDesign.DetailsOnMe thods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RE CORD.StabilityThermal. MaterialsAndMethods.A nyOtherInformationOn MaterialsAndMethodsIn clTables
Results and discussion		Header 1	ENDPOINT_STUDY_RE CORD.StabilityThermal. ResultsAndDiscussion

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For thermal stability study		Header 2	ENDPOINT_STUDY_RE CORD.StabilityThermal. ResultsAndDiscussion.T hermalStability
Test substance thermally stable	Indicate whether the test substance was stable under the test conditions or not. Describe any details on results in field 'Any other information on results incl. tables'. The melting point should be recorded in the corresponding data entry screen.	Closed list with remarks	ENDPOINT_STUDY_RE CORD.StabilityThermal. ResultsAndDiscussion.T hermalStability.TestSub stanceThermallyStable
Operating temperature	Provide the operating temperature or range at which the thermal stability was determined. For comparison reason, the data should be recorded in degree C. If reported in other units, it is recommended to convert to °C. By copying this block of fields both the original and converted value(s) can be entered. If analytical method is used to determine the concentration, provide method details including method validation data in fields 'Any other information on materials and methods incl. tables' and attach all relevant chromatograms in field 'Attached background materials'.		ENDPOINT_STUDY_RE CORD.StabilityThermal. ResultsAndDiscussion.T hermalStability.Operati ngTemperature
Key result	Set this flag for identifying the key	Check box	ENDPOINT_STUDY_RE CORD.StabilityThermal.

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	information which is of potential relevance for hazard/risk assessment or classification purpose.		ResultsAndDiscussion.ThermalStability.OperatingTemperature.KeyResult
Operating temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.ThermalStability.OperatingTemperature.OperatingTemp
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.ThermalStability.OperatingTemperature.RemarksOnResults
Operating temperature			
Sublimation	Indicate whether sublimation occurred.	Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.ThermalStability.Sublimation
Transformation products	Transformation products BLOCK (OHT) Indicate whether transformation products	Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.T

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	occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.		hermalStability.TransformationProducts
For study on stability to sunlight		Header 2	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.StudyOnStability
Test substance stable to sunlight	Indicate whether the test substance was stable under the test conditions or not. Describe any details on results in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.StudyOnStability.StableToSunlight
For study on stability to metals		Header 2	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.StabilityToMetals
Test substance stable to metals / metal ions	Indicate whether the test substance was sensitive to contact with metals or metal ions under the test conditions or not. Describe any details on results in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.StabilityToMetals.StableToMetals
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityThermal.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityThermal.ApplicantSummaryAndConclusion
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2.8 Technical characteristics of the plant protection product - Endpoint study record

<p>Purpose</p> <p>The technical characteristics of the plant protection product shall be determined and reported at appropriate concentrations.</p> <p>The technical characteristics of the preparation must be determined to permit a decision to be made as to its acceptability.</p> <p>If tests have to be performed, they must be done at temperatures compatible with survival of the micro-organism.</p>
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ENDPOINT_STUDY_RECORD.TechnicalCharacteristics – v.7.1 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	<p>Administrative data – common block</p> <p>This document can be used to report the following endpoints. Complete a separate document for each endpoint</p> <p>Wettability Persistent foaming Suspensibility, suspension stability Dry sieve test and wet sieve test Particle size distribution, dust content, attrition and mechanical stability Hardness and integrity Emulsifiability, re-emulsifiability, emulsion stability Flowability, pourability (rinsability), dustability. Where necessary data</p>	Header 1	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.AdministrativeData

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	waiving can be used for an endpoint.		
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.DataSource.Reference
Study type	This field is used to specify which technical characteristic is going to be described in the study.	Open list	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.DataSource.StudyType
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussions		Header 1	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.ResultsAndDiscussions
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.ResultsAndDiscussions.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.OverallRemarksAttachments

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2.8.4 Degree of dissolution and dilution stability – Endpoint study record

Purpose:

The degree of dissolution and dilution stability is required for solid products that are dissolved in water or diluted (e.g. water soluble bags, tablets).

The dilution stability is determined to ensure that water-soluble preparations dissolve readily and/or, when diluted, produce stable solutions without precipitation, flocculation, etc. The results submitted should fully describe the appearance and amount of any separation or sediment.

Any deviation from the guideline method used or any other special consideration should be reported.

ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability v2.2 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.DataSource
Materials and methods	Material and methods – common block Applicable Test guideline: CIPAC Method MT 41.1: Dilution stability of aqueous solutions or CIPAC Method MT 179: Water soluble granules, degree of dissolution and solution stability or CIPAC Method MT: Solution properties of ST formulations	Header 1	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.MaterialsAndMethods.TestMaterials

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Study design		Header 2	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.MaterialsAndMethods.StudyDesign
Analytical method	Select the analytical method used as appropriate. Multiple selection is possible. If not listed, select 'other' and specify. In the supplementary remarks field, provide method validation. As appropriate attach all relevant chromatograms.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on methods	Provide details on the methods including analytical method, method validation data and all relevant chromatograms (attach as appropriate) particularly if no guideline was used. If the test substance appears 'insoluble' in water, provide the detection limit of the analytical method. Also provide the purity of water used. If an estimation method was used (to be indicated in field 'Test result type') state the equation(s)	Text area	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.MaterialsAndMethods.StudyDesign.DetailsOnMethods

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	applied to calculate the water solubility.		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion
Degree of dissolution	The information is required for products used in a water soluble bag and for all tablets. The dissolution rate should be demonstrated regarding tablets and products used in water soluble bags in water and that the formulation dissolves or disperses rapidly. The test should be performed at the highest concentration. If necessary, copy this block of fields for all conditions at which the degree of dissolution was determined. Provide all other information in the field 'Details on results'.		ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DegreeOfDissolution
Key result	Set this flag for identifying the key information which is of potential	Check box	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DegreeOfDissolution.KeyResult

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	<p>relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance on how to use this field.</p>		
Flow time (sec)	<p>Enter a single numeric value in the numeric field. The unit is predefined (sec).</p>	Decimal	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DegreeOfDissolution.FlowTimeSec
Concentration	<p>Indicate the concentration of the powder in the suspension. Select a unit from the drop-down list.</p>	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DegreeOfDissolution.Concentration
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DegreeOfDissolution.RemarksOnResults
Degree of dissolution			

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Dilution stability	<p>The dilution stability is determined to ensure that water-soluble preparations dissolve readily and/or, when diluted, produce stable solutions without precipitation, flocculation, etc. The results submitted should fully describe the appearance and amount of any separation or sediment. The test should be conducted at the maximum in use concentration specified on the label. The acceptable limit would be a 'trace' of separate material after 30 minutes. If necessary, copy this block of fields for all conditions at which dilution stability was determined. Provide all other information in the field 'Details on results'.</p>		<p>ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStabilityMT41</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for</p>	<p>Check box</p>	<p>ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStabilityMT41.KeyResult</p>

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	hazard/risk assessment or classification purpose. Consult any programme-specific guidance on how to use this field.		
Presence of separated material	Indicate the presence of separate material. Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStabilityMT41.PresenceOfSeparatedMaterial
Concentration	Indicate the concentration of the powder in the suspension. Select a unit from the drop-down list.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStabilityMT41.Concentration
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStabilityMT41.RemarksOnResults
Dilution stability			
Dilution stability	The dilution stability is determined to		ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStabili

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	<p>ensure that water-soluble preparations dissolve readily and/or, when diluted, produce stable solutions without precipitation, flocculation, etc. The results submitted should fully describe the appearance and amount of any separation or sediment. The test should be conducted at the maximum in use concentration specified on the label. If necessary, copy this block of fields for all conditions at which dilution stability was determined. Provide all other information in the field 'Details on results'.</p>		<p>ty.ResultsAndDiscussion.DilutionStability</p>
Key result		Check box	<p>ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.KeyResult</p>
Concentration	<p>Indicate the concentration of the sample. The amount of sample should correspond to the highest concentration recommended in the directions for</p>	Unit measure with Open List (Decimal)	<p>ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Concentration</p>

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	use of the product. Select a unit from the drop-down list.		
5 min test		Row label	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test5Min
Presence of sediment	Indicate the presence of sediment after standing for 5 min. Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test5Min.PresenceOfSediment5min
Amount of residue (g)	Indicate amount of dry residue. The unit is predefined (g).	Decimal	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test5Min.AmountOfResidueG
Repeatability r	Indicate repeatability in the 5 min test. Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test5Min.RepeatabilityR
Reproducibility R	Indicate reproducibility in the 5 min test. Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test5Min.ReproducibilityR
18 h test		Row label	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test18H
Presence of sediment	Indicate the presence of sediment after standing for 18 h. Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test18H.PresenceOfSediment18h
Amount of residue (g)	Indicate amount of dry residue. The unit is predefined (g).	Decimal	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test18H.AmountOfResidueG
Repeatability r	Indicate repeatability in the	Closed list	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStabili

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	18 h test. Select from drop-down list.		ty.ResultsAndDiscussion.DilutionStability.Test18H.RepeatabilityR
Reproducibility R	Indicate reproducibility in the 18 h test. Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test18H.ReproducibilityR
Remarks on result		Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DilutionStability.Test18H.RemarksOnResult
Dilution stability			
Details on results		Text area	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DegreeOfDissolutionAndDilutionStability.ApplicantSummaryAndConclusion

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2.9 Physical, chemical and biological compatibility with other products including plant protection products with which its use is to be authorized – Endpoint study record

Purpose

- The physical compatibility of recommended tank mixes must be determined and reported.
- The chemical compatibility of recommended tank mixes must be determined and reported except where examination of the individual properties of the preparations would establish beyond reasonable doubt that there is no possibility of reaction taking place. In such cases it is sufficient to provide that information as justification for not practically determining the chemical compatibility.
- The biological compatibility of tank mixes must be determined and reported. Effects (e.g. antagonism, fungicidal effects) on the activity of the micro-organism after mixing with other micro-organisms or chemicals must be described. The possible interaction of the plant protection product with other chemical products to be applied on the crops under the expected condition of use of the preparation shall be investigated, based on the efficacy data. Intervals between application of the biological pesticide and chemical pesticides shall be specified, if appropriate, in order to avoid loss of efficacy

ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility – v.6.0 (Final) [August 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block Separate documents can be created for each endpoint (Biological, Chemical, Physical) Use the remarks to indicate the endpoint covered by the document	Header 1	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.DataSource.Reference
Type of compatibility of the biocidal product with other products including biocidal products with which its use is to be authorised		Header 2	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.DataSource.TypeOfCompatibility

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	This field is used to specify which type of compatibility is going to be described in the study. Physical compatibility or chemical compatibility is the available option. For microorganisms biological compatibility can also be indicated	Closed list	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.DataSource.TypeOfCompatibility.TypeOfCompatibilityLabel
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussions		Header 1	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.ResultsAndDiscussions
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.ResultsAndDiscussions.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RE CORD.PhysicalChemical Compatibility.ApplicantS ummaryAndConclusion
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2.10 Adherence and distribution to seeds, and additional physico-chemical information - Endpoint summary

<p>Purpose Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details for other physico-chemical properties which cannot be reported in other summaries. This would include adherence and distribution to seeds</p>
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ENDPOINT_SUMMARY.AdditionalPhysicoChemical – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY. AdditionalPhysicoChemical.AdministrativeDataS ummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY. AdditionalPhysicoChemical.Discussion

2.10 Adherence and distribution to seeds, and additional physico-chemical information - Endpoint study record

<p>Purpose This document can be used to summarize studies on any Physical, chemical and technical properties of the plant protection product not covered by the other documents in this section This document covers the following endpoints In the case of plant protection products for seed treatment, both distribution and adhesion shall be determined and reported. In the case of preparations for seed treatment, both distribution and adhesion must be investigated and reported; in the case of distribution in accordance with CIPAC Method MT 175.</p>

ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical – v.6.4 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RE CORD.AdditionalPhysico Chemical.Administrative Data

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.DataSource.Reference
Materials and methods	Material and methods – common block Note: MT 175 - Determination of seed-to-seed uniformity of distribution for liquid seed-treatment formulations MT 83 - Seed adhesion test for powders for seed treatment are relevant for the Adherence and distribution to seeds endpoint	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ResultsAndDiscussion
Results	Report the results of the test(s) performed. Include an interpretation of the	Text area	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ResultsAndDiscussion.Results

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	<p>results in field 'Conclusions'. Report amount of pesticide detected on seeds after for each condition tested (e.g. shaking or tumbling) or the uniformity of the formulation from seed to seed (colormetric measurement)</p>		
Any other information on results incl. tables	<p>Any other information on results incl. tables Block</p>	Header 2	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	<p>Overall remarks, attachments – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.OverallRemarksAttachments
Applicant's summary and conclusion	<p>Applicants summary and conclusion – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ApplicantSummaryAndConclusion
Conclusions	<p>Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any).</p>	Text area	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ApplicantSummaryAndConclusion.Conclusions
Executive summary	<p>If relevant for the respective regulatory programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document.</p>	Rich text area	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ApplicantSummaryAndConclusion.ExecutiveSummary

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3 Data on application

3.1 Use of the plant protection product (GAP)

Purpose

The Good Agricultural Practice (GAP) describes the intended or registered safe use of plant protection products, according to Article 3(2)(a) of Regulation (EC) No 396/2005. The different fields required to define the use of the plant protection product unambiguously are listed in Table 4.

The IUCLID GAP form implements the following data requirements:

- Details of intended use
- Application rate
- Method of application
- Number and timing of applications and duration of protection
- Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

If you click on the red plus sign next to the header 'x Good agricultural practices (GAP)' you can create a new GAP. A name will be assigned automatically to the GAP, containing as default name 'Good agricultural practices (GAP)' followed by a dot and three numbers.

Please note that separate GAP documents need to be created, if the GAPs differ in one or more of the parameters. For some fields multiple options from a picklist can be selected. Please read carefully below the instructions to see whether in a given case a separate GAP document needs to be created or whether it is appropriate to describe the different use options in one form.

FLEXIBLE_RECORD.GAP – v. 1.8		
Name	Instructions	Field Path
Administrative data	The general rules on confidentiality requests apply in setting the flags Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	FLEXIBLE_RECORD.GAP.AdministrativeDataSummary
Product	This field is mandatory. Click on the red plus sign to link the GAP to an existing mixture composition (see Introduction). If no mixture dossier or dataset is available in the inventory, create first a new one and add a mixture composition. In general, the GAP has to be completed for the target a.s., i.e. the a.s. for which the approval/renewal of the approval is requested or for which the MRL application is submitted. If the plant protection product contains a second (non-target) a.s., it is not required to provide a separate GAP form for the second a.s.	FLEXIBLE_RECORD.GAP.AdministrativeDataSummary.Product
Description of key information	The free text field can be used to give a short explanation/description of the GAP. This information is not mandatory. For GAPs that involve different application methods at different growth stages (e.g. drench application at sowing followed by foliar application at a later growth stage), the	FLEXIBLE_RECORD.GAP.KeyInformation

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	<p>GAP should be split in separate GAPs (in the example the first GAP being the drench application, the second the foliar use). In this field, the GAPs belonging to a sequential application should be labelled (e.g. GAP 1 of 2, GAP 2 of 2). The field should also be used to label representative uses (relevant for applications on the approval or the renewal of the approval). For existing uses (D2 document), indicate "authorised use" in this field; otherwise the document will be interpreted as for an intended use (D1).</p>	
<p>Crop/treated object</p>	<p>Information on the crop/treated object is mandatory. A picklist is implemented to describe the crop or object to be treated with the plant protection product. The picklist is based on EPPO codes which have been enhanced with additional information to make them more user friendly/self-explanatory. The extended EPPO codes cover the following types of information:</p> <ul style="list-style-type: none"> • the first 5 digits are the EPPO code (see EPPO Plant Protection Thesaurus at http://eppt.eppo.org) (e.g. PIBSX), • followed by the scientific name of the crop (PIBSX <i>Pisum sativum</i>); • in brackets, the crop name in English is reported (PIBSX <i>Pisum sativum</i> (English pea)); • for the most important crops, the corresponding food code of the MRL food classification is reported after a dash (code of Annex I of Regulation (EC) No 396/2005). For some crops, more than one food code is applicable (e.g. PIBSX <i>Pisum sativum</i> (English pea) - 0260030, 0260040, 0300030). <p>In the current version of IUCLID, the link with the food codes of the MRL legislation has been established only for codes listed in Part A of Annex I of Regulation (EC) No 396/2005; food codes listed in Part B of Annex I to, the connection to the crop code has not yet been implemented (the link will be included in the next release of IUCLID). Please note that not for all codes all four name elements are available.</p> <p>To find the codes for the crop/object, the user can either use the hierarchy search tool which requests to choose between crops or treated products. Alternatively, a text string (e.g. the EPPO code, the scientific name) can be directly entered in the search window, resulting in a subset of matching options.</p> <p>In the hierarchy tool, the user should first select between the two highest hierarchy levels 'crops' or 'treated product'. Treated products is relevant only for post-harvest uses and for uses on non-crop objects (e.g. treatment of railways).</p>	<p>FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.Cr op</p>

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	<p>As a next step, a text string (EPPO code, scientific name, name of the crop in English or the food code of the MRL legislation) can be inserted. EPPO codes matching with the search term are displayed in yellow, and the user should select the relevant one.</p> <p>For post-harvest treatment of food products, two EPPO codes are available (HARFO and HARPO) which were combined with all food codes (Part A) of Annex I of Regulation (EC) No 396/2005:</p> <ul style="list-style-type: none"> • If the treatment with the plant protection product is intended on the fresh harvested product (e.g. oranges), the code combining HARFO and the respective food code should be selected (e.g. 3HARFO – Oranges – 011020). • For GAPs describing a use on a processed harvested product (e.g. raisins), the code HARPO in combination with the food code should be used (e.g. 3HARPO – Table grapes – 0151010). <p>In general, codes for crop groups should not be selected. Instead the EPPO codes for the individual crops should be chosen. A multiple selection of crop codes is allowed, only if all parameters of the GAP are identical for all crops selected. If the GAPs differ for the individual crops in one or several fields, a separate GAP form needs to be completed. To facilitate the work to complete separate GAP forms, an existing GAP can be copied and modified for the respective parameters (see 1.3.6).</p> <p>Further remarks on the crop/treated product can be reported in a free text field, which is created when the user clicks on the symbol .</p> <p>Remarks are necessary to specify whether food or feed has been in contact with the plant protection product indirectly if one of the following codes for treated product has been selected:</p> <table border="1" data-bbox="451 1354 1144 1638"> <tr> <td>3IRRWO</td> <td>irrigation water (treatment of)</td> </tr> <tr> <td>BULBO</td> <td>bulbs, tubers, corms (treatment of)</td> </tr> <tr> <td>PLABO</td> <td>plant base (treatment of)</td> </tr> <tr> <td>SEEDO</td> <td>seeds (treatment of)</td> </tr> <tr> <td>WOUNO</td> <td>wounds (treatment of)</td> </tr> </table>	3IRRWO	irrigation water (treatment of)	BULBO	bulbs, tubers, corms (treatment of)	PLABO	plant base (treatment of)	SEEDO	seeds (treatment of)	WOUNO	wounds (treatment of)	
3IRRWO	irrigation water (treatment of)											
BULBO	bulbs, tubers, corms (treatment of)											
PLABO	plant base (treatment of)											
SEEDO	seeds (treatment of)											
WOUNO	wounds (treatment of)											
<p>Genetical modification of crop</p>	<p>If relevant, describe variety of genetically modified crops on which the use of the plant protection product is intended to be used or authorised.</p>	<p>FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.Ge neticalModification</p>										

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<p>Crop destination(s)</p>	<p>The field is not mandatory. Please select the relevant EPPO code for crop destination. Multiple selection is allowed (e.g. grown for animal consumption (3ANICD) and grown for human consumption (3HCOND)). In remarks field more details on the crop destination can be described. See also EPPO code list https://gd.eppo.int/PPPUse/3CRODK</p>	<p>FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.CropDestination</p>
<p>Authorisation zone</p>	<p>Please select the relevant Authorisation zone from the picklist. The assignment of countries to the different zones for the authorisation of products can be found in Annex I of Regulation (EC) No 1107/2009. Please note that multiple selection of codes is not allowed. Information on the authorisation zone is not mandatory if at least one country has been selected in the field 'Country or territory'. If no information is provided in 'Country or territory' and in 'Authorisation zone', it is assumed that the GAP is relevant for all EU zones.</p>	<p>FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.AuthorisationZone</p>
<p>MRL zone</p>	<p>Select the MRL zone in which the GAP is intended. The assignment of the individual European countries to the zones can be found in the guidance document SANTE/2019/12752 (https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-d.pdf) (or a subsequent revision of this document).</p>	<p>FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.MrIZone</p>
<p>Country or territory</p>	<p>Select the country or the territory related to the GAP. The selection of more than one country is possible if the same GAP applies.</p>	<p>FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.CountryOrTerritory</p>
<p>Crop location (F/G/I)</p>	<p>This data element is mandatory for GAPs that refer to crops (children codes listed under crops and children codes of '3HARVO harvested crops (treatment of)'). For other GAPs the field should remain empty. The available picklist contains EPPO codes with detailed descriptions of the cases. I: Code to be used for crops grown or stored in closed walk-in buildings. This code includes for example mushroom houses and structures for witloof chicory or rhubarb forcing. G: A walk-in, static, closed place of crops production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and</p>	<p>FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.CropLocation</p>

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	<p>prevents release of plant protection products into the environment.</p> <p>F: Fields and other structures which do not prevent release of plant protection products into the environment.</p> <p>For crops grown outdoor (F), more details can be reported using the more specific subcodes. The detailed description of the subcodes is provided in the picklist.</p>	
Target organisms	Select 'New item' and compile the block consisting of 'Scientific name', 'Common name', 'Development stage of target pest' and 'Development stage of target plant'. See detailed descriptions below.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.TargetOrganisms
Scientific name	<p>Select the appropriate code and scientific name from picklist. The picklist is based on the EPPO list (https://gd.eppo.int/taxon/).</p> <p>At least one target organism needs to be defined in a GAP. It is possible to select more than one target organism, if the GAP parameters are identical for the different target organisms.</p> <p>If the target organism is not listed, select 'other' and specify.</p> <p>If a scientific name is not relevant or not known, select 'no data'.</p> <p>Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required according to a programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. 'I.1.1.1 (EU BPD)'.</p> <p>Please make sure that the scientific name entered in this field matches with the organism described in the field 'Common name'.</p>	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.TargetOrganisms.ScientificName
Common name	Please add the common name of the target organism in this field that matches with the Scientific name.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.TargetOrganisms.CommonName
Development stage of target pest	<p>For insecticide and fungicide uses, indicate the developmental stage of the target organism/pest (e.g. development stage of the insect or of the disease for diseases caused by fungi).</p> <p>If no appropriate description is available in the list, select 'other:' and specify the development stage in the remarks.</p> <p>If the development stage is not known or not further specified, select 'not specified'.</p> <p>If the development stage is not relevant/applicable, leave field empty.</p> <p>Multiple selection of terms is allowed.</p>	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.TargetOrganisms.DevelopmentStagePest

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<p>Development stage of target plant</p>	<p>For herbicide uses, indicate the developmental stage of the target plant. In the picklist BBCH codes have been implemented. Although these codes have been developed for describing the development stages of crops, they can be used in analogy for the target plants. Any remarks can be entered in the supplementary remarks field, for instance an alternative description of the developmental stage which is not available in the picklist.</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.TargetOrganisms.DevelopmentStagePlant</p>																
<p>Major/minor use</p>	<p>Select the applicable code from the picklist. Minor use according to Art. 51 of Regulation (EC) No 1107/2009 should be flagged as 'minor use'. Other EU uses are to be considered as major use (combination of crop/target organism). Please note that GAPS need to be split in separate documents/GAP forms, if the different crops selected in the field 'crops/treated object' would require different the flags (e.g. not all crops are major crops). The field is not relevant for uses in third countries (e.g. import tolerances).</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.MajorMinorUse</p>																
<p>Application target</p>	<p>The target to be treated can be selected from a picklist. The following terms are implemented:</p> <table border="1" data-bbox="456 982 1146 1682"> <thead> <tr> <th>Picklist value</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>Foliage/Plant</td> <td>Application to a plant or the leaves of a plant.</td> </tr> <tr> <td>Seed / Seed Pieces</td> <td>Application to a small object produced by a plant from which a new plant can grow.</td> </tr> <tr> <td>Propagation Stock</td> <td>Application to a specimens of a plant, used for breeding by natural processes from the parent stock.</td> </tr> <tr> <td>Root/Bulb</td> <td>Applications (such as dip applications) to a rootball (the compact mass of roots), or bulb (a part of plants that functions as a food storage during dormancy).</td> </tr> <tr> <td>Bark</td> <td>Application to or into the tough, protective outer sheath of the trunk, branches, and twigs of a tree or woody shrub.</td> </tr> <tr> <td>Stump / cut stem</td> <td>Application to the recently cut of a tree or woody shrub (excludes cut flowers).</td> </tr> <tr> <td>Containerized plant</td> <td>Application to a plant and soil grown in a movable container.</td> </tr> </tbody> </table>	Picklist value	Description	Foliage/Plant	Application to a plant or the leaves of a plant.	Seed / Seed Pieces	Application to a small object produced by a plant from which a new plant can grow.	Propagation Stock	Application to a specimens of a plant, used for breeding by natural processes from the parent stock.	Root/Bulb	Applications (such as dip applications) to a rootball (the compact mass of roots), or bulb (a part of plants that functions as a food storage during dormancy).	Bark	Application to or into the tough, protective outer sheath of the trunk, branches, and twigs of a tree or woody shrub.	Stump / cut stem	Application to the recently cut of a tree or woody shrub (excludes cut flowers).	Containerized plant	Application to a plant and soil grown in a movable container.	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ApplicationTarget</p>
Picklist value	Description																	
Foliage/Plant	Application to a plant or the leaves of a plant.																	
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Surface	Application to the interior and/or exterior boundaries of an inanimate object. Examples of these types of applications include boat hulls, countertops, hives, nests, etc.																			
Non-porous Surface	Surfaces where liquids will not absorb such as ceramic, porcelain, glass, metal, plastic/vinyl, rubber, stainless steel.																			
Porous Surface	Surfaces where a liquid is likely to absorb such as fabric, drywall, composition board surfaces, paint films and surfaces, plaster surfaces, and wood.																			
other																				
Method of application	Information on the application method is mandatory. Select the application technique relevant for the GAP from the picklist. Please note that in future releases of IUCLID, EPPO codes will be implemented, which are currently under development. If appropriate, the new EPPO codes (Treatments, 3TREAK) can be reported in the remarks field. More than one term can be selected, if the application techniques belong to the same application type/class.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ApplicationMethod																		

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	<p>If different application methods are foreseen on a crop (e.g. seed treatment followed by foliar broadcast), two uses should be described as separate GAPs, including in the remarks that the two GAPs are combined.</p>	
Growth stage and season	<p>Click on 'New item' and compile the block of fields that comprises the following fields: Growth stage of crop (first application), Growth stage of crop (last application), Treatment season. If the GAP foresees treatments at different treatment windows (e.g. first treatment window before flowering, second treatment window after flowering), the block can be repeated. Information on the growth stage is mandatory if the GAP refers to a crop; if the GAP refers to treatment of non-crop objects (children of 3NOCFO), it is not required; if the GAP refers to treatment of harvested crops (children codes of 3HARVO), BBCH 99 should be entered; if the GAP refers to children codes of 3CRPAO (treatment of crop parts), it is not required. If number of applications is greater than 1, the information on the growth stage needs to be reported for the first and the last application. Treatment season is not mandatory.</p>	<p>FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason</p>
Growth stage of crop (first application)	<p>This field is intended to describe the growth stage of the crop at the first treatment with the plant protection product. The picklist offers the BBCH codes which describe the phenomenologically similar growth stages of all mono- and dicotyledonous plant species (source: BBCH Monograph edited by Uwe Meier, Julius Kühn-Institut, 2018, doi: 10.5073/20180906-074619). Select the growth stage of the crop at first application. If a treatment is foreseen at one specified growth stage, select the BBCH code only in this field (Growth stage of crop (first application)). For a range, also select the relevant BBCH code in the field 'Growth stage of crop (last application)'. If necessary, more details on the treatment timing shall be reported in remarks (e.g. a description of the timing/growth stage at the application to specify more detailed the timing of the application (e.g. pre-plant, before transplant, etc.)). The letters in bracket after the description of the crop development show to which plant group the respective definition refers. (D = Dicotyledons, M = Monocotyledons, G = Gramineae, P = Perennial plants, V = Development from vegetative parts or propagated organs).</p>	<p>FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason.GrowthStageCropFirst</p>

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	Please note that BBCH codes 71 to 79 is not used, if the main fruit growth happens in principal growth stage 8.	
Growth stage of crop (last application)	Please select from the picklist the growth stage of crop at last application. See above (Growth stage of crop (first application)) for further details.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason.GrowthStageCropLast
Treatment season	For autumn/winter sown crops, report whether the treatment is foreseen in autumn/winter or in spring/summer. Multiple selection is allowed. If necessary, any other restrictions for the treatment season can be reported in the remarks field, selecting the option 'other:'	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason.TreatmentSeason
Number of applications (range)	Information on the number of applications is mandatory. Report the number of applications (e.g. 1 – 3). If only one treatment is foreseen, report '1' in the lower numeric field.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ApplicationsRange
Re-treatment interval (in days)	Enter the interval between treatments (re-treatment interval); if relevant, a range for minimum interval and maximum interval between treatments, expressed in days, can be reported.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.RetreatmentInterval
Application rate per treatment (product) – range	Mandatory information. For reporting the application rate, follow the recommendations on dose expression for plant protection products (EPPO General Standard PPI/239(3)). Enter the numeric value in the first numeric field corresponding the lower application rate (for the formulation) per treatment. Use the second numeric field to report the upper application rate per treatment. Select the most appropriate unit to express the application rate. For applications on crops, the application rate should preferably be expressed as application rate per hectare. See also below application rate per treatment for target a.s. (range).	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ApplicationRatePerTreatment
Remarks on application rate	Any further explanations related to the application rate can be provided in this field. For 3-dimensional crops, the application rate expressed on leaf wall area can be reported in addition to the application rate reported per hectare.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.RemarksOnApplicationRate

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<p>Water amount per treatment / spray volume</p>	<p>For products applied after dilution with water, the minimum and maximum amount of water used in spray application (spray volume) should be reported.</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.WaterAmountPerTreatment</p>
<p>Concentration of formulation in dilution</p>	<p>For products applied after dilution with water, report the concentration of the formulation in the solution.</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ConcentrationFormulationDilution</p>
<p>Safener/ synergist/ adjuvant added</p>	<p>Is a safener/synergist/adjuvant intended to be added to the tank mix? If yes, the information on the type and the amount of safener/synergist/adjuvant is mandatory. Please indicate whether the addition of the safener/synergist/adjuvant is mandatory or whether it is only recommended. Indicate the safener/synergist/additive type, the name and the amount added to the tank mix (volume (%)). See also EPPO standard PP1/291(1).</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.SafenerSynergistAdjuvant</p>
<p>Application rate per treatment for target a.s. (range)</p>	<p>It is mandatory to report the application rate for the target a.s. The field is intended to specify the application rate for the target active substance (i.e. the a.s. defined in the active substance dataset (EU PPP Active substance information) of the IUCLID dossier). For reporting the application rate, follow the recommendations on dose expression for plant protection products (EPPO General Standard PPI/239(3)). Enter the numeric value in the first numeric field corresponding the lower application rate per treatment. Use the second numeric field to report the upper application rate per treatment. If the formulation contains a variant of the active substance (e.g. an ester), the application rate should be expressed for the a.s. (not for the variant!). Example for a variant: the formulation contains quizalofop-P-terfuryl which is a variant of the a.s. quizalofop-P. In the field defining the application rate for the target a.s. the application rate should be expressed as quizalofop-P. The factor to recalculate the application rate of quizalofop-P-terfuryl (molecular weight 428.9) to quizalofop-P (molecular weight 344.7) is derived as the ratio of the molecular weight ($344.7/428.9=0.804$).</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ApplicationRateForTarget</p>

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Maximum seasonal application rate (a.s.)	<p>Please note that in the current version of IUCLID the field name might be misleading: in the future release the name will be changed to 'Maximum annual application rate' to avoid any confusion.</p> <p>If restrictions need to be defined for the annual application rate (in case of crops which have more than one harvest per season), please report the maximum annual application rate for the active substance. The application rate should be reported for the a.s. (not the variant).</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.SeasonalApplication</p>
Treatment window (for dispensers)	<p>For dispensers or similar application forms, the duration of treatment window needs to be reported.</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.TreatmentWindowDispensers</p>
Seeding rate (maximum)	<p>Field relevant for seed treatments only.</p> <p>Enter the seeding rate: For crops where the seeds are usually sold by number of units (e.g. sugar beet, maize, sunflower), the seeding rate should be expressed as unit/ha (unit is usually 100.000 individual kernel). For seeds sold by weight (e.g. cereals the seeding rate is normally expressed in kg or g seeds /ha or m²).</p> <p>If 'other:' is selected as unit, describe the seeding rate unit in the remarks.</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.MaxSeedingRate</p>
Planting density	<p>The field is not mandatory.</p> <p>Describe the planting density (number of plants per ha or m²).</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.PlantingDensity</p>
Pre-harvest interval	<p>Mandatory field. Specify the minimum pre-harvest interval (PHI) in days (i.e. the minimum time between the last treatment of a crop and the harvest). This field should also be used to describe the time between post-harvest treatment of a food/feed item and the placement on the market. Enter a single numeric value. The qualifier '>' can be used together with a PHI to describe treatments at early development stages of the crop where the PHI cannot be specified more accurately. 'Not applicable' can be selected where the pesticide is applied to empty storage rooms, or for treatment of fields after harvest. In case 'not applicable' is selected, further clarifications need to be provided in the field 'additional information'.</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.PreharvestInterval</p>
Re-entry period livestock	<p>The field is not mandatory.</p> <p>This field should be used to describe the minimum re-entry period (hours/days) for livestock, i.e. the time that needs to elapse before animals may enter treated pastures.</p>	<p>FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails</p>

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		ails.ReentryPeriodLivestock
Withholding period animal feed	The field is not mandatory. This field is intended to define the minimum time (in days) between harvest of a feed crop and the use of the feed.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.WithholdingPeriod
Re-entry period	The field is not mandatory. Describe the minimum re-entry period (in days or hours) for workers in the field/room treated with pesticide, in order to safeguard human health. If no re-entry period is defined/required, select 'not applicable'.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ReentryPeriod
Waiting period handling treated product	The field is not mandatory. This field is intended to describe the minimum waiting periods (hours/days) that need to be respected between treatment and handling of treated products (e.g. handling of products after fumigation).	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.WaitingPeriod
Ventilation practices	The field is not mandatory. If relevant, please describe the ventilation practices to be carried out after indoor treatments, to safeguard human health.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.VentilationPractices
Plant-back interval	The field is not mandatory. If relevant, please describe the plant-back interval (expressed as days) that has to be respected (e.g. in case of crop failure) before the planting of succeeding crops is allowed.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.PlantbackInterval
Restrictions	The field is not mandatory. If relevant, please report any relevant restrictions that would have an impact on the risk assessment e.g.: <ul style="list-style-type: none"> - geographical restrictions, - restriction related to use of other a.s., - maximum number of applications per season for a.s. belonging to the same group (e.g. dithiocarbamates, triazoles), - restrictions for rotational crops, - PPE, - buffer zones, - temperature range at application, - soil incorporation depth and time, - restricted soil type, - restriction to crops grown in artificial substrate, 	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.Restrictions

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	<ul style="list-style-type: none"> - restriction to be used only in crops grown in hydroponic systems, - restriction to crops grown in pots/no connection to natural soil, - restrictions to be used in crops up to a certain crop height, - minimum percent soil organic matter, - restrictions to protect pollinators, - restriction regarding application equipment. 	
Type of user	The field is not mandatory. Please select one or several terms from the picklist (professional/non-professional/other:). If other is selected, please provide more details in the remark filed.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.TypeOfUser
Additional information	Any relevant information on the GAP that cannot be reported in any of the data fields above should be entered in this field.	FLEXIBLE_RECORD. GAP.AdditionalInformation

3.2 Effects on harmful organisms- Endpoint summary

<p>Purpose: This document covers the following endpoints:</p> <ul style="list-style-type: none"> - Function - Effects on harmful organisms / Information of target organisms - Mode of action - Information on (possible) occurrence of resistance development and appropriate management strategies

ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganism - v5.0			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.AdministrativeDataSummary
	Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the	Confidentiality	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.AdministrativeDataSummary.DataProtection

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	<p>confidentiality flag is set.</p> <p>Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants</p>		
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.Discussion

3.2 Effects on harmful organisms - Endpoint study record

<p>Purpose: This document covers the following endpoints:</p> <ul style="list-style-type: none"> - Function - Effects on harmful organisms / Information of target organisms - Mode of action - Information on (possible) occurrence of resistance development and appropriate management strategies

ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms v.7.3			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.AdministrativeData
General information		Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation
Background information	<p>Use this field to include any background information, if required, or any relevant introductory remark. Leave field empty if not applicable. Do not include information for which specific fields are provided.</p> <p>PURPOSE OF THIS</p>	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.BackgroundInformation

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	<p>TEMPLATE: This template can be used for recording general information on the effectiveness of an active substance or a biocidal product, together with its active substances (as required by the relevant legislation). For products, efficacy studies should be reported using the corresponding template 'Efficacy data'. For active substances, the effectiveness achieved or claimed should be briefly described in this template. If required or sensible such description can be supported by including summary table(s) which give an overview of relevant efficacy studies performed with a product or products. As appropriate, the general information can be provided in one record or in several individual records. For instance, one record may be sensible if several target organisms, but same function and product type are addressed. Separate records may be sensible for addressing different types of target organisms and functions.</p>		
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	Note that this template focuses primarily on biocides. If used for other than this purpose additional pieces of information may have to be added in several fields. Consult the programme-specific guidance on the details to be included.		
Pest / target organisms to be controlled		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled
Target organisms	Specify the target organism(s) to be controlled. Repeat this block of fields as necessary. Due to the great number of possible target organisms this picklist is not exhaustive. If the species name is not listed, choose an appropriate superior term (e.g. 'Acaridae:') and specify by entering free text in the related field. If organism is not listed at all, choose 'other:' and enter the name or several names in a row in the related text field.		ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms
Scientific name	Select appropriate scientific name from picklist. If not listed, select 'other' and specify. If not given/known, select 'no data'. See also instructions on this	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.ScientificName

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	<p>block of fields. Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses.</p>		
Common name	<p>Select appropriate common name from picklist. If not listed, select 'other' and specify. If not given/known, select 'no data'. See also instructions on this block of fields. Any remarks can be entered in the supplementary remarks field.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.CommonName
Developmental stage of target pest	<p>Indicate the developmental stage of the target organism. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty. Any remarks can be entered in the supplementary remarks field, for instance any code for the developmental stage if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.DevelopmentalStage
Developmental stage of target plant	<p>Indicate the developmental stage of</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.DevelopmentalStage

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	the target organism. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty.		nstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.DevelopmentalStageOfTargetPlant
Target organisms			
Products, organisms or objects to be protected / under study		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.ProductsOrganismsOrObjectsToBeProtectedUnderStudy
Organisms (to be protected) or treated materials	Describe and specify the organism(s) or materials(s) / object(s) to be protected, e.g. human, pets, farm animals, fur- and wool-bearing animals, drinking water, hard surface material , porous surface.	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.ProductsOrganismsOrObjectsToBeProtectedUnderStudy.OrganismsToBeProtectedOrTreatedMaterials
Information on intended use and application		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication
Function addressed	Indicate the function of the substance. Multiple selection is possible for indicating additional functions provided they relate to the same product type indicated in the next field. However, it may be sensible or required according to legislation-specific guidance to use separate records for each function. Any remarks can be entered in the	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FunctionAddressed

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	<p>supplementary remarks field, for instance any code for the function if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses.</p>		
Product type	<p>Indicate the product type in which the active substance is intended to be included or which is envisaged for the product. In case of multiple product types use separate records for each of them. Note that only product types related to EU BPD are listed. For other legislations, choose 'other:' and specify in the related text field.</p>	Open list	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.ProductType
Field of use envisaged / User	<p>If the use conditions are fully described in a GAP document in the dossier, it is sufficient to make reference to the GAP document which describes the use. IUCLID document name and UUID. If this is provided additional information on the use of the product already described in the GAP document does not need to be provided</p>	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FieldOfUseEnvisagedUser
Information on application of biocidal product		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfBiocidalProduct

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Method of application	See Field of use envisaged / User	Multi select open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfBiocidalProduct.MethodOfApplication
Details on application	See Field of use envisaged / User	Text template	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfBiocidalProduct.DetailsOnApplication
General information on effectiveness		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness
Effects on target organisms	The effects on the target organisms required for the claimed efficacy should be described and specified if possible for each use and method of application if these have different effects, including any effect-concentration dependences or the possible existence of a threshold concentration of the active substance. Refer to the instructions given in the relevant guidance documents. In case of a submission of an active substance the effectiveness achieved or claimed should be briefly described. If required or sensible such	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.EffectsOnTargetOrganisms

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	<p>description can be supported by including summary table(s) which give an overview of relevant efficacy studies performed with a product or products. Upload predefined table(s) in the rich text field 'Overall remarks'. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). To show possible differences, the use, i.e. product type and method of application of the biocidal product(s) envisaged should also be given. For products, efficacy studies should be reported using the corresponding template 'Efficacy data'.</p>		
<p>Mode of action</p>	<p>Indicate the principles of the mode of action for the function indicated in above field, e.g. 'acute toxin: contact poison'. If not listed, select 'other' and specify. Any remarks can be entered in the supplementary remarks field, for instance any code for the mode of action if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses..</p>	<p>Open list with remarks</p>	<p>ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ModeAction</p>

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<p>Details on mode of action</p>	<p>For the function indicated in above field, indicate the principles of the mode of action; e.g. 'contact poison' or 'stomach poison'. Briefly describe the biochemical and physiological mechanisms, e.g. 'cholinesterase inhibition' and the biochemical pathway and specify any time delay between application and effect. Use the freetext template as appropriate (delete/add elements). For further instructions refer to the relevant guidance documents</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.DetailsOnModeOfAction</p>
<p>(Possible) Occurrence of resistance</p>	<p>Indicate whether resistance can possibly develop including cross-resistance. As appropriate include an appraisal of the information gained from the efficacy studies.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.PossibleOccurrenceOfResistance</p>
<p>Management strategies to avoid resistance</p>	<p>Describe any appropriate management strategies towards the minimization of the development of resistance.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ManagementStrategiesToAvoidResistance</p>
<p>Any other known limitations and management strategies</p>	<p>As applicable describe any other known limitations and relevant management strategies towards them.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.AnyOtherKnownL</p>

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			imitationsAndManagementStrategies
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion
Details on results		Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ApplicantSummaryAndConclusion

4 Further information on the plant protection product

4.2 Recommended methods and precautions- Flexible record

<p>Purpose: The risks likely to arise and the methods and procedures to minimize the hazards arising, shall be specified.</p> <ul style="list-style-type: none"> - Recommended methods and precautions. - Emergency measures in the case of an accident, - Procedures for destruction or decontamination - Neutralization procedure - Controlled incineration - Procedures for cleaning application equipment
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FLEXIBLE_RECORD.ProtectionMeasures v.5.3 (Final)			
Name	Instructions	Data type	Field path

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Administrative data	See Administrative data	Header 1	FLEXIBLE_RECORD.ProtectionMeasures.AdministrativeDataSummary
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.ProtectionMeasures.AdministrativeDataSummary.DataProtection
Instructions for use	Not relevant for pesticides: Instructions for use must be described in the Good Agricultural Practice (GAP) document	Header 1	FLEXIBLE_RECORD.ProtectionMeasures.InstructionsForUse
Measures to protect humans, animals and the environment		Header 1	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect
Recommended methods and precautions concerning storage of active substance/product; shelf-life of product	<p>Substance: The field is used to identify all methods and precautions concerning the storage of an active substance.</p> <p>Product: The field is used to identify all methods and precautions concerning the storage of a product, including the shelf life of a product. The shelf life of product under normal conditions of storage should be reported.</p>	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.RecommendedMethodsAndPrecautionsConcerningStorage
Recommended methods and precautions concerning handling and transport	Describe all methods and precautions concerning handling and transport.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.RecommendedMethodsAndPrecautionsConcerningHandling

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	<p>Detailed handling procedures for the storage, at both warehouse and user level of plant protection products must be provided</p> <p>Where appropriate, the nature and characteristics of protective clothing and equipment proposed shall be provided. The data provided shall be sufficient to evaluate the suitability and effectiveness under realistic conditions of use (for example field or glasshouse circumstances)</p>		
Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.	<p>The field is used to identify all methods and precautions concerning fire, and all possible consequences of it. Where available, information on combustion products shall be provided</p>	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.RecommendedMethodsAndPrecautionsConcerningFire
Particulars of likely direct or indirect adverse effects	<p>The field is used to identify all direct or indirect adverse effects.</p>	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.ParticularsOfLikelyDirect
First aid instructions, antidotes	<p>Not relevant for pesticides: Report information on poisoning and treatment in the Medical data document (Section 5.9 Medical data or Section 5.2.6</p>	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.FirstAidInstructionsAntidotes

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	Direct observation, e.g. clinical cases).		
Emergency measures to protect environment in case of accident	<p>Provide information on Emergency measures in the case of an accident and detailed procedures to be followed in the event of an emergency, whether arising during transport, storage or use</p> <p>This could include containment of spillages, decontamination of areas, vehicles and buildings, disposal of damaged packaging, absorbents and other materials, protection of emergency workers and residents, including bystanders</p> <p>In the case of micro-organisms, Information on procedures for rendering the micro-organism harmless in the environment (e.g. water or soil) in case of an accident must be provided</p>	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.EnvironmentInCaseOfAccident
Control measures of repellents or poison included in the product, to prevent action against non-target organisms	The field is used to identify all measures that could be taken to prevent action against non-target organisms when using the product.	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresOfRepellents

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(relevant for products only)			
Procedures, if any, for cleaning application equipment (relevant for products only)	The field is used to provide procedures for cleaning the equipment or machinery used for the application of the product. If there is no need to use any additional equipment, please indicate it clearly. Washing and cleaning of protective equipment should also be described (where relevant). The effectiveness of cleaning procedures shall be described in detail.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.Procedures
Possibility of destruction or decontamination following release in or on the following:		Header 1	FLEXIBLE_RECORD.ProtectionMeasures.PossibilityOfDestructionOrDecontamination
Air	Describe possibility of destruction or decontamination following release in the air. Release to air is not relevant for microorganisms	Text area	FLEXIBLE_RECORD.ProtectionMeasures.PossibilityOfDestructionOrDecontamination.Air
Water, including drinking water	Describe possibility of destruction or decontamination following release in or on the water, including drinking water.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.PossibilityOfDestructionOrDecontamination.Water
Soil	Describe possibility of destruction or decontamination following release in or on the soil.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.PossibilityOfDestructionOrDecontamination.Soil
Procedures for waste management	Procedures for destruction and	Header 1	FLEXIBLE_RECORD.ProtectionMeasures.Proced

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<p>of active substance/product, and if appropriate, its packaging:</p>	<p>decontamination shall be developed for both small quantities (user level) and large quantities (warehouse level).</p>		<p>uresForWasteManagement</p>
<p>Possibility of reuse or recycling</p>	<p>Substance: The field is used to identify possibility of reuse or recycling of the active substance and to describe relevant procedures for industry or professional users.</p> <p>Product: The field is used to identify possibility of reuse or recycling of the product and its packaging and to describe relevant procedures for industry, trained professional, professional users and non-professional users</p> <p>Procedures to preclude or minimise the generation of waste or leftovers shall be provided.</p>	<p>Text area</p>	<p>FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.PossibilityOfReuseOrRecycling</p>
<p>Neutralisation procedure and possibility of neutralisation of effects</p>	<p>Neutralisation procedures (such as by reaction with other substances to form less toxic compounds) for use in the event of accidental spillages shall be described, where such procedures can be applied</p>	<p>Text area</p>	<p>FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.PossibilityOfNeutralisationOfEffects</p>

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	<p>Methods to dispose safely of the micro-organism or, where necessary, to kill it prior to disposal, and methods to dispose of contaminated packaging and contaminated materials, must be fully described</p> <p>Substance: The field is used to identify possibility of neutralisation of effects caused by the active substance and to describe relevant procedures for industry or professional users.</p> <p>Product: The field is used to identify possibility of neutralisation of effects caused by the product and its packaging and to describe relevant procedures for industry, trained professional, professional users and non-professional users.</p>		
<p>Conditions for controlled discharge including leachate qualities on disposal</p>	<p>Substance: The field is used to describe conditions for controlled discharge of the active substance, including leachate qualities on disposal. Detailed description of all relevant procedures for industry or</p>	<p>Text area</p>	<p>FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.ConditionsForControllerDischarge</p>

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	<p>professional users should be done.</p> <p>Product: The field is used to describe conditions for controlled discharge of the product, including leachate qualities on disposal. Detailed description of all relevant procedures for industry, trained professional, professional users and non-professional users, should be done.</p>		
Conditions for controlled incineration	<p>If controlled incineration is not the preferred method of disposal, full information on the alternative method of safe disposal used shall be provided (in the other fields in this section)</p> <p>Substance: The field is used to describe conditions for controlled incineration of the active substance. Detailed description of all relevant procedures for industry or professional users should be done.</p> <p>Product: The field is used to describe conditions for controlled incineration of the product. Detailed description of all relevant procedures for</p>	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.ConditionsForControllerIncineration

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	industry, trained professional, professional users and non-professional users, should be done.		
Instructions for safe disposal of the product and its packaging for different groups of users (relevant for biocidal products only)	Not relevant for pesticides	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.InstructionsForSafeDisposal
Additional information		Header 1	FLEXIBLE_RECORD.ProtectionMeasures.AdditionalInformation
Reference	Indicate the bibliographic reference of the study report or publication used to support any or all of the points above. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search. Always enter the primary reference in the first block of fields or sort it to the first position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study	Literature reference list	FLEXIBLE_RECORD.ProtectionMeasures.AdditionalInformation.Reference

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	<p>or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study.</p> <p>A sanitised version of the report must be uploaded in the literature reference for publication, the original version can be included if it differs from the sanitised version</p> <p>Safety datasheets in the form of literature references can be added as references in this field</p>		
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Links to support material:

Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)

<http://data.europa.eu/eli/dir/2010/75/2011-01-06>

4.4 Packaging, compatibility of the plant protection product with proposed packaging materials – Flexible record

Purpose

(i) Packaging to be used must be fully described and specified in terms of the materials used, manner of construction (e.g. extruded, welded, etc.), size and capacity, size of opening, type of closure and seals. It must be designed in accordance with the criteria and guidelines specified in the FAO 'Guidelines for the Packaging of Pesticides'. (ii) The suitability of the packaging, including closures, in terms of its strength, leakproofness and resistance to normal transport and handling, must be determined and reported in accordance with ADR methods 3552, 3553, 3560, 3554, 3555, 3556, 3558, or appropriate ADR Methods for intermediate bulk containers, and, where for the preparation child-resistant closures are required, in accordance with ISO standard 8317. (iii) The resistance of the packaging material to its contents must be reported in accordance with GIFAP Monograph No 17.

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FLEXIBLE_RECORD.Packaging – v.3.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data		Header 1	FLEXIBLE_RECORD.Packaging.AdministrativeDataSummary
	Use this field to set flags for confidentiality and regulatory purpose(s).	Confidentiality	FLEXIBLE_RECORD.Packaging.AdministrativeDataSummary.DataProtection
Packaging		Header 1	FLEXIBLE_RECORD.Packaging.Packaging
If relevant, specify to which product(s) it applies:	<p>The field is used to identify the product(s) being a member (members) of a product family (in case the concept applies), to which the packaging description in this very endpoint applies. After clicking the golden chain the list of product composition from section product composition. The applicant should select the relevant product composition(s). It is possible to include different sizes of packaging in one record, as long as the packaging shape is similar and the material is identical.</p> <p>One product (member of the product family) can use several types of packaging, therefore the same product composition can be linked to several packaging documents. If the product is not a member of a product</p>	Endpoint reference list	FLEXIBLE_RECORD.Packaging.Packaging.UseOurComposition

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	family, this field remains empty.		
Type of packaging in contact with the product (container type)	This field is used to indicate the material of container that is in contact with a product. Please note that the secondary packaging should be indicated, if relevant, in the field Description of secondary packaging (not in contact with the product), and not here.	Open list	FLEXIBLE_RECORD.Packaging.Packaging.TypeOfPackaging
Size of packaging in contact with the product (container size)			FLEXIBLE_RECORD.Packaging.Packaging.SizeOfPackagingInContactWithTheProductContainerSize
Size of packaging in contact with the product (container size)	This field is used to indicate the size of the container that is in contact with a product. The minimum and maximum size must be indicated. Please note that the secondary packaging should be indicated, if relevant, in the field Description of secondary packaging (not in contact with the product).	Range with open list (Decimal)	FLEXIBLE_RECORD.Packaging.Packaging.SizeOfPackagingInContactWithTheProductContainerSize.SizeOfPackaging
Size of packaging in contact with the product (container size)			
Material of packaging in contact with the product (container material)	This field is used to indicate the material of the container that is in contact with a product. Additional text fields are available, when option plastic composite, metal, or	Open list	FLEXIBLE_RECORD.Packaging.Packaging.MaterialOfPackaging

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	<p>other is selected. Please note that the secondary packaging should be indicated, if relevant, in the field Description of secondary packaging (not in contact with the product).</p>		
Compatibility of the product with the packaging materials proposed to be in contact with the product	<p>This field is used to give any information that is needed to prove that the packaging material is compatible with the product.</p>	Text area	FLEXIBLE_RECORD.Packaging.Packaging.Compatibility
Further description of the packaging in contact with the product	<p>If needed, give any further explanations concerning the packaging being in contact with product.</p>	Text area	FLEXIBLE_RECORD.Packaging.Packaging.FurtherDescription
Safety features of the packaging	<p>Any information that is related to safety of packaging should be described here, i.e. existence of a child-resistant fastening, labelling in such way that hazard can be identified by people with special needs, etc.).</p>	Text area	FLEXIBLE_RECORD.Packaging.Packaging.SafetyFeaturesOfThePackaging
Description of the secondary packaging (not in contact with the product)	<p>This field is used to describe the secondary packaging, i.e. boxes, tape, and pallet stretch film that was used to get a product to a retail or distribution centre.</p>	Text area	FLEXIBLE_RECORD.Packaging.Packaging.Description
Packaging related attachments			FLEXIBLE_RECORD.Packaging.Packaging.PackagingRelatedAttachments
Type of attachment	<p>This field is used to indicate the type of document which is attached. The option</p>	Open list	FLEXIBLE_RECORD.Packaging.Packaging.PackagingRelatedAttachments.TypeOfAttachment

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	'other' is available, with specification in the additional text field. This is the correct place to attach a picture of label of packaging.		
Attached document	After clicking on the blue paper-clip icon , the green plus icon appears, and the window Select files to add opens. The chosen attachment is added by pressing Open. Please note that more than one document can be attached by adding the rows to the table using the button +.	Single file attachment	FLEXIBLE_RECORD.Packaging.Packaging.PackagingRelatedAttachments.AttachedDocument
Remarks	If needed, give any further explanations concerning attachment(s).	Text	FLEXIBLE_RECORD.Packaging.Packaging.PackagingRelatedAttachments.Remarks
Packaging related attachments			
Additional information on packaging		Rich text area	FLEXIBLE_RECORD.Packaging.Packaging.AdditionalInfo

5 Analytical methods - Endpoint summary

<p>Purpose Summary information of to the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, which could be: recovery, selectivity (specificity), calibration, precision (repeatability, reproducibility), limit of detection (LOD), and limit of quantitation (LOQ). (http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en)</p>

ENDPOINT_SUMMARY.AnalyticalMethods – v.3.0 (Final) [July 2020]			
Name	Instructions	Data Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.AdministrativeDataSummary

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	<p>Description of key information: Provide an assessment of the suitability of the proposed methods for monitoring and enforcement. Note Further information on residue definitions and LOQs can be provided in Proposed residue definitions document and Proposed maximum residue levels document in the Residues Section</p>		
Additional information	<p>Discussion (Header 1) – common block Attached (sanitised) documents for publication: The file "Template 4.1 - Template for the overview table for analytical methods for risk assessment" (https://doi.org/10.5281/zenodo.4556992) shall be uploaded here.</p>	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.Discussion

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Links to support documents

OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39. (ENV/JM/MONO(2007)17)

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)17&oclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&oclanguage=en)

EU guidance document for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99).

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_res_pre-reg-cont-monitor.pdf

EU guidance document on analytical methods for the determination of residues (Post-registration monitoring and control) (SANCO/825/00 rev. 8.1, 2010)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_res_post-reg-cont-monitor.pdf

Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods (SANTE/2017/10632)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_wrkdoc_2017-10632.pdf

5 Analytical Methods - Endpoint study record

Purpose:

The provisions of this Section cover analytical methods used for the generation of pre-approval data and required for post-approval control and monitoring purposes. Descriptions of methods shall be provided and include details of equipment, materials and conditions used. On request, the following shall be provided: (a) analytical standards of the purified active substance; (b) samples of the active substance as manufactured; (c) analytical standards of relevant metabolites and all other components included in all monitoring residue definitions; (d) samples of reference substances for the relevant impurities. Where possible, the standards referred to in points (a) and (c) shall be made commercially available and, on request, the distributing company shall be named.

It is recommended to use the cross-reference feature in endpoint study records to cross link to a specific analytical method endpoint study record used in the study.

ENDPOINT_STUDY_RECORD.AnalyticalMethods – v6.3 (Final) [September 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. DataSource.Reference
Background		Header 1	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. Background
Background and information	Use this field to include any background information, if required, or any relevant introductory remarks on the study summary. Leave field empty if not applicable. Do not include information for which specific fields are provided. For instance, include any background information on the test substance in fields on 'Test materials'. PURPOSE OF THIS TEMPLATE: This template can be used for summarising analytical methods for determining a given substance in various matrices. Depending on the requirements of the relevant legislation, methods for the following matrices may have to be recorded: soil, sediment, suspended particulates, air, water (including drinking water), animal and human body fluids and tissues, plants, plant products, food and feedingstuffs, formulated product, other.	Multi-line text	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. Background.Background Information
Materials and methods	Material and methods – common block Guideline: Select the applicable test guideline, e.g. EU guidance document on analytical methods for the analysis of technical material and preparation (SANCO/3030/99 rev. 4) Residues: EU guidance document on analytical methods for the determination of residues (Post-registration monitoring and control) (SANCO/825/00 rev. 8.1, 2010) EU guidance document for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99 rev. 4). OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39.	Header 1	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods
Matrix / medium	Indicate the medium for which the analytical method is described. In the supplementary remarks field, you can	Multi select	ENDPOINT_STUDY_REC ORD.AnalyticalMethods.

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	<p>add explanations as appropriate.</p> <p>Note: The picklist is not descriptive as to whether analytical methods have to be submitted for each of the matrices provided in the picklist. If the methods for several matrices can be summarised in one record, you can copy this field for indicating the respective matrices.</p>	<p>t open list with rema rks</p>	<p>MaterialsAndMethods.M atrixMedium</p>
Test material	<p>Test material – common block</p>	<p>Head er 2</p>	<p>ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.Te stMaterials</p>
Principles of analytical methods		<p>Head er 2</p>	<p>ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.Pri nciplesOfAnalyticalMeth ods</p>
Instrument / detector	<p>Indicate the instrument / detector used for the quantitative analysis including the type of detector, e.g. 'HPLC-UV'. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on analytical data collection method'.</p> <p>Note: If a residue analytical method is recorded, the instrument/detector used for the so-called data collection or data-gathering method should be specified here. Data collection method is the analytical method used to collect quantitative residue data by analysing the analyte(s) in the matrices. This method can be identical with or differ from the so-called enforcement method which has to be recorded under the heading 'Enforcement method (if applicable)'. Enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides.</p>	<p>Multi selec t open list</p>	<p>ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.Pri nciplesOfAnalyticalMeth ods.InstrumentDetector</p>
Details on analytical method	<p>Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product:') in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report.</p> <p>Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the</p>	<p>Text temp late</p>	<p>ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.Pri nciplesOfAnalyticalMeth ods.DetailsOnAnalytical Method</p>

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	terms 'data collection method' and 'enforcement method' see help text for field 'Instrument / detector'. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Enforcement method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable
Instrument / detector for enforcement method	If no enforcement method is proposed or required, ignore this field. An enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides. If such a method is proposed indicate the instrument / detector used in the enforcement method. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on data enforcement method'.	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.InstrumentDetectorForEnforcementMethod
Details on enforcement method	'Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. "parent compound", "parent and transformation products" or "transformation product:") in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report. Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms "data collection method" and "enforcement method" see help text for field "Instrument / detector". Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.DetailsOnEnforcementMethod
Confirmatory method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable

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Instrument / detector for confirmatory method	'If not applicable, ignore this field. If a confirmatory method was used (i.e. applying techniques to demonstrate specificity in case the original method is not highly specific), indicate the instrument / detector used. Note: Not all picklist items may be relevant for a confirmatory technique. Multiple selection is possible if more than one method needs to be specified. Give any further details in field "Details on data confirmatory method".'	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.InstrumentDetectorForConfirmatoryMethod
Details on confirmatory method	Briefly describe further details on the principles of the confirmatory method if any. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Multi-line text	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.DetailsOnConfirmatoryMethod
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion
Recovery results and characteristics of analytical method		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod
Recovery results	Indicate the compound (analyte) addressed (e.g. 'parent compound', 'parent and transformation products' or 'transformation product:'). Report the recovery rates at each level (e.g. at spiking level 1, spiking level 2 etc.) at the limit of quantification and give the mean % recovery and the relative standard deviation in % including the number of recovery studies. Include a brief evaluation of the repeatability of the method (e.g. 'These values demonstrate that the method has satisfactory repeatability.')	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.RecoveryResults

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	Use freetext template and delete/add elements as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Characteristics of analytical method	For each compound (analyte) addressed (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product:'), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio. Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms 'data collection method' and 'enforcement method' see help text for field 'Instrument / detector'. Provide information on extractability studies. Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.CharacteristicsOfAnalyticalMethod
Results using enforcement method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod
Recovery results (enforcement method)	If not applicable, ignore this field. If an enforcement method is proposed which is different from the analytical method described as general analytical method (or 'data-gathering method' in residue analysis), indicate the compound (analyte) addressed (e.g. 'parent compound', 'parent and transformation products' or 'transformation product:'). Report the recovery rates at each level (e.g. at spiking level 1, spiking level 2 etc.) at the limit of quantification and	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.RecoveryResults

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	<p>give the mean % recovery and the relative standard deviation in % including the number of recovery studies. Include a brief evaluation of the repeatability of the method (e.g. 'These values demonstrate that the method has satisfactory repeatability.')</p> <p>Use freetext template and delete/add elements as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>		
Characteristics of enforcement method	<p>If not applicable, ignore this field. If an enforcement method is proposed which is different from the analytical method described as general analytical method (or 'data-gathering method' in residue analysis), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio for each compound (analyte) addressed (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product:').</p> <p>Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.CharacteristicsOfEnforcementMethod
Independent laboratory validation (if applicable)	<p>If not applicable, ignore this field. If applicable (as for enforcement methods), discuss the independent laboratory validation (ILV) in terms of whether or not it was conducted according to guideline specifications. Discuss any method modifications that may impact the analyses of the residues (e.g., altered LOQ) that are suggested by the independent laboratory. Alternatively, include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation

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Independent laboratory validation	If not applicable, ignore this field. If applicable (as for enforcement methods), discuss the independent laboratory validation (ILV) in terms of whether or not it was conducted according to guideline specifications. Discuss any method modifications that may impact the analyses of the residues (e.g., altered LOQ) that are suggested by the independent laboratory. Alternatively, include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation.IndependentLaboratoryValidation
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Further information on extractability can be uploaded in the attachment fields.	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ApplicantSummaryAndConclusion

Links to support material:

OECD GUIDANCE DOCUMENT ON PESTICIDE RESIDUE ANALYTICAL METHODS

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)17&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en)

Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013.

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_3030.pdf

[Guidance document on analytical quality control and method validation procedures for pesticide residues analysis in food and feed](#) - SANTE/12682/2019 - 1 January 2020

[Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods](#) – SANTE 2017/10632 rev.3, 22 November 2017

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6 Efficacy data - Endpoint summary

Purpose:

Conclusions on the evaluation of the nature and extent of benefits that accrue following use of the plant protection product, in comparison to an untreated control and where they exist in comparison to suitable reference products and damage thresholds, and to define its conditions of use.

ENDPOINT_SUMMARY.Efficacy – v.1.0 (Final) [August 2020]

Field name	Instructions	Field path
Administrative data		ENDPOINT_SUMMARY.Efficacy.AdministrativeDataSummary
Description of key information	<p>Enter a short description of key findings of the submitted studies including</p> <ul style="list-style-type: none"> -target organisms -overview of use descriptions -overview of crops and locations where testing was performed -minimum effective dose -possible indications of development of resistance, unintended side effects or other limitations observed <p>Do the number of trials to be conducted and reported reflect factors such as the extent to which the properties of the active substances it contains are known and on the range of conditions that arise, including variability in plant health conditions, climatic differences, the range of agricultural practices, the uniformity of the crops, the mode of application</p>	ENDPOINT_SUMMARY.Efficacy.KeyInformation

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	<p>the type of harmful organism and the type of plant protection product?</p> <p>Statement on whether representative uses GAPs are supported.</p>	
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency <p>-the possible reasons for differentiating results when several studies were identified to be relevant for the assessment.</p> <p>A summary table of the performance of [a.s.] against named targets representative of proposed uses at the proposed dose (and including data from reduced doses) and a summary table of crop safety of [a.s.] on named crops representative of proposed uses at the proposed dose and twice the proposed dose can be included here.</p>	<p>ENDPOINT_SUMMARY.Efficacy. Discussion.Discussion</p>

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	<p>Where appropriate a separate table should be included showing the results of any yielded crop safety trials should also be added</p> <p>If there is no additional information to be reported this field may be left empty.</p>	
Attached background material		ENDPOINT_SUMMARY.Efficacy.Discussion.AttachedBackgroundMaterial
Attached document	The original version of the Attached (sanitised) documents for publication should be uploaded here (only if different from the sanitised version).	ENDPOINT_SUMMARY.Efficacy.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	ENDPOINT_SUMMARY.Efficacy.Discussion.AttachedBackgroundMaterial.Remarks
Attached (sanitised) documents for publication	Additional information to support the summary can be included here (this will be published).	ENDPOINT_SUMMARY.Efficacy.Discussion.AttachedSanitisedDocsForPublication

Links to support material:

Guidance Document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products SANCO/10054/2013-rev.3 11 July 2013

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6 Efficacy data - Endpoint study record

Purpose:

Information to evaluate the nature and extent of benefits that accrue following use of the plant protection product, in comparison to an untreated control and where they exist in comparison to suitable reference products and damage thresholds, and to define its conditions of use

Sufficient data shall be submitted to confirm that patterns of use of the plant protection product tested are representative of the regions and the range of conditions likely to be encountered in the regions concerned, for which its use is intended.

The performance of the active substance against target organisms, representative for the proposed uses at the proposed dose, as well as , observations on undesirable or unintended side-effects and information on the development of resistance should be presented by the applicant in the dossier, as part of study summaries for all field trials, and where appropriate, in tabular format.

ENDPOINT_STUDY_RECORD.EfficacyData - v.6.3 (Final) [September 2020]

Field name	Instructions	Field path
Test guideline	<p>Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.</p> <p>Copy this block of fields for specifying more than one guideline (e.g. EPPO standard series PP1).</p>	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.Guideline
Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - 'according to guideline' (if a given test guideline was followed); 	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.Guideline.Qualifier

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	<ul style="list-style-type: none"> - 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline'); - 'no guideline available' (if so, fill in field 'Principles of method if other than guideline'). - 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'). 	
Guideline	<p>Select the applicable test guideline, e.g. 'EPPO Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.</p> <p>If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.</p>	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.Guideline.Guideline
Version / remarks	<p>In this text field, you can enter any remarks as applicable, particularly:</p>	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.Guideline.VersionRemarks

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	<ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given test guideline); - To indicate if the study was performed prior to the adoption of the test guideline specified; - To indicate if the methodology used was based on an extension of the test guideline specified; - To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. 	
Deviations	In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.Guideline.Deviation
Principles of method if other than guideline	If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate, use either of the pre-defined freetext template options for 'Method of non-guideline study'. Delete / add elements and edit text set	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.MethodNoGuideline

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	<p>in square brackets [...] as appropriate.</p> <p>For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed.</p> <p>Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate.</p>	
GLP compliance	<p>Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes' is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed.</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.GLPComplianceStatement</p>
Compliance with quality	<p>Indicate whether the efficacy data were generated according to GEP (Good Experimental Practice) or by an officially recognised organisation. If this is not the case, enter 'no', 'no data' or 'not required' as applicable. Refer to programme-specific guidance as to the required adherence to official recognition, GEP or other quality assurance standards.</p> <p>In the supplementary remarks field, you can add explanations</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.ComplianceWithQualityStandards</p>

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	as appropriate, e.g. provide a certificate number. If required, attach any (signed and dated) certificate or quality assurance statement in field 'Attached background material'.	
Test material		ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Formulation type	<p>Indicate the type of formulation used in the study. If not listed, select 'other' and specify.</p> <p>Any remarks can be entered in the supplementary remarks field, for instance any code for the formulation type, if required, according to programme-specific guidance.</p>	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.TestMaterials.FormulationType
Analytical monitoring	Indicate whether the active substance was monitored during the test.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.TestMaterials.AnalyticalMonitoring
Details on sampling and analytical methods	If the amount of test material exposed to the organisms was monitored, provide details on sampling and analytical methods used.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.TestMaterials.DetailsOnSamplingAndAnalyticalMethods
Pest / target organisms to be controlled		ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled
Test / target organisms	Specify the test / target organism(s) used in the study. Repeat this block of fields for specifying all organisms covered	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.TestTargetOrganisms

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	<p>by this record. Due to the great number of possible test organisms this picklist is not exhaustive. If the species name is not listed, choose an appropriate superior term (e.g. 'Acaridae:') and specify by entering free text in the related field. If organism is not listed at all, choose 'other:' and enter the name or several names in a row in the related text field. If this template is used to summarise several efficacy studies (e.g. by attaching summary tables as described in the instructions for field 'Background information'), this block of fields can be left empty. However, if the number of different species is reasonable, you should also specify them here in addition to the summary tables. This will allow searching.</p>	
Scientific name	<p>Select appropriate scientific name from picklist. If not listed, select 'other' and specify. The EPPO database can be consulted to retrieve the scientific names of target organisms. If not given/known, select 'no data'. See also instructions on this block of fields.</p> <p>Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required so according to programme-specific guidance.</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.TestTargetOrganisms.ScientificName</p>
Common name	<p>Select appropriate common name from picklist. If not listed,</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.</p>

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	<p>select 'other' and specify; if necessary, consult the EPPO database. If not given/known, select 'no data'. See also instructions on this block of fields.</p> <p>Any remarks can be entered in the supplementary remarks field.</p>	PestTargetOrganismsToBeControlled.TestTargetOrganisms.CommonName
Developmental stage of target pest	<p>Indicate the developmental stage of the target organism. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty.</p>	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.TestTargetOrganisms.DevelopmentalStage
Developmental stage of target plant	<p>Indicate the developmental stage of the target organism. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty. For herbicide uses, indicate the developmental stage of the target plant.</p> <p>In the picklist BBCH codes have been implemented. Although these codes have been developed for describing the development stages of crops, they used in analogy for the target plants.</p>	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.TestTargetOrganisms.DevelopmentalStageOfTargetPlant
Details on test / target organisms	<p>Freetext template:</p> <p>Option 1 For single species test</p> <ul style="list-style-type: none"> - Strain: - Source: - Wild type: [yes/no] 	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.DetailsOnTestTargetOrganisms

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	<ul style="list-style-type: none"> - Any selection pressure (sensitivity, resistance): - Pre-conditioning / rearing conditions: - Weight at study initiation: - Age (of the stadium) at study initiation: [mixed age population /] - Numbers used in the test: - Sex of those used in the test (where appropriate): - Other (specify): <p>Option 2 For test with microbial population / inoculum</p> <ul style="list-style-type: none"> - Nature: - Origin: - Collection / storage of samples: - Preparation of inoculum for exposure: - Pretreatment: - Initial biomass / density / numbers in test system: - Other (specify): 	
<p>Products (materials), organisms or objects to be protected / under study</p>		<p>ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.ProductsMaterialsOrganismsOrObjectsToBeProtectedUnderStudy</p>
<p>Organisms (to be protected) or treated materials</p>	<p>If applicable, describe and specify the organism(s) or materials(s) / object(s) to be</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.ProductsMaterialsOrganismsOrObjectsToBeProtectedUnderStudy.</p>

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	protected as addressed by these efficacy data.	OrganismsToBeProtectedOrTreatedMaterials
Study design		ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.StudyDesign
Total exposure duration (contact time)	If applicable, enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.StudyDesign.TotalExposureDurationContactTime
Remarks	Enter any remarks related to the total exposure duration.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.StudyDesign.Remarks
Mode of efficacy assessment	<p>Freetext template:</p> <ul style="list-style-type: none"> - Effects investigated: - Method for recording / scoring effects: - Intervals of examination: - Post monitoring of test organisms <p>Describe the parameter(s) measured for assessing efficacy and the intervals of measurements, together with the scoring or assessment system used. Where appropriate, describe the duration of post monitoring of test organisms.</p>	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.StudyDesign.ModeOfEfficacyAssessment

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	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary.	
Method of application	<p>Indicate the method of application. If not listed, select 'other' and specify.</p> <p>Any remarks can be entered in the supplementary remarks field.</p>	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.StudyDesign.MethodOfApplication
Details on study design	<p>Option 1 Optional items for laboratory studies</p> <p>FURTHER DETAILS ON APPLICATION</p> <ul style="list-style-type: none"> - Application/dosage and dilution rates (incl. dose justification): - Adjuvans/vehicle/carrier: - Presence of interfering substances: - Other (specify) <p>MONITORING OF TEST SUBSTANCE</p> <ul style="list-style-type: none"> - Monitoring of active substance concentration: - Method of analysis: <p>TEST CHAMBER / DEVICE</p> <ul style="list-style-type: none"> - Type and design of test chamber / device: - Other (specify) <p>SURFACE TYPES</p>	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.StudyDesign.DetailsOnStudyDesign

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	<ul style="list-style-type: none"> - Type: [porous, non-porous] <p>TEST CONDITIONS</p> <ul style="list-style-type: none"> - Temperature: - Rel. humidity: - Aeration: - Light cycles during test: - pH: - Water hardness: - Soil type: - Nutrient supply conditions: - Any additions or alterations to the test environment during the study: - Other (specify) <p>INITIAL DENSITY/NUMBERS OF TARGET ORGANISMS</p> <ul style="list-style-type: none"> - Initial density / numbers in test system: - Frequency or level of infestation / infection: <p>REPLICATES</p> <ul style="list-style-type: none"> - Number of replicates: <p>CONTROLS</p> <ul style="list-style-type: none"> - Untreated controls: - Positive controls (reference substance): <p>OTHER (specify):</p> <p>Option 2 Optional items for field and use tests</p>	
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	<p>APPLICATION</p> <ul style="list-style-type: none"> - Type/method of application: - Code of application type (if any): - Application rates: More than one application rate can be needed. Number and timing of applications have to be stated. The water volume/ha should also be stated. - Application/dosage and dilution rates (incl. dose justification): - Adjuvans/vehicle/carrier: - Other (specify) <p>EXPERIMENTAL DESIGN</p> <ul style="list-style-type: none"> - <p>GEOGRAPHICAL LOCATION</p> <ul style="list-style-type: none"> - For efficacy evaluation the EPPO climatic zones should be mentioned <p>TEST CONDITIONS / METEOROLOGICAL INFORMATION</p> <p>INITIAL DENSITY/NUMBERS OF TARGET ORGANISMS</p> <ul style="list-style-type: none"> - Initial density / numbers in test system: - Frequency or level of infestation / infection: <p>REPLICATES</p> <ul style="list-style-type: none"> - Number of replicates: 	
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	<p>CONTROLS</p> <ul style="list-style-type: none"> - Untreated controls: - Positive controls (reference substance): <p>OTHER (specify):</p>	
Any other information on materials and methods incl. tables	<p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation</p>
Results and discussion		<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion</p>
Efficacy / performance assessment	<p>If possible, indicate the percentage of efficacy in terms of control, reduction, damage of target organisms or reduction of disease caused by pest organisms. Copy this field block for entering more than one efficacy level (e.g. based on other exposure duration, dose or endpoint) if necessary.</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.EfficacyPerformanceAssessment</p>

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	Note: It may be appropriate to record, in this block of fields, only the mean level of effect or control. If the effect level relates to several test runs (i.e. test conditions), give ranges.	
Efficacy parameter	Indicate the efficacy / performance parameter (e.g. % kill/cidal activity) to which the index entered in the next field refers to.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.EfficacyPerformanceAssessment.EfficacyParameter
Efficacy (in %)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.EfficacyPerformanceAssessment.Efficacy
Time to produce effect	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.EfficacyPerformanceAssessment.TimeToProduceEffect
Treatment	If efficacy results are recorded for different treatment conditions (by repeating this block of fields), briefly indicate the type of treatment/application the results refer to. Specify dose, application rate, duration, etc.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.EfficacyPerformanceAssessment.Treatment
Interfering substances	Indicate if interfering substances were present. If 'yes' is selected,	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.

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	briefly specify in the supplementary remarks field.	EfficacyPerformanceAssessment.InterferingSubstances
Remarks on result	<ul style="list-style-type: none"> - not determinable - not determinable because of methodological limitations - not measured/tested - other: <p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.EfficacyPerformanceAssessment.RemarksOnResults
Minimum effective dose	If determined, provide the minimum effective dose, i.e. the dose or concentration considered the minimum necessary to achieve sufficient efficacy against the target organism(s) studied under the treatment conditions indicated. Copy this field block for recording values based on different treatment conditions if necessary	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.MinimumEffectiveDose
Minimum effective dose	Enter minimum effective dose.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.MinimumEffectiveDose.MinimumEffectiveDose

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<p>Time to produce effect</p>	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.MinimumEffectiveDose.TimeToProduceEffect</p>
<p>Treatment</p>	<p>If efficacy results are recorded for different treatment conditions (by repeating this block of fields), briefly indicate the type of treatment/application the results refer to. Specify dose, application rate, duration, etc.</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.MinimumEffectiveDose.Treatment</p>
<p>Interfering substances</p>	<p>Indicate if interfering substances were present. If 'yes' is selected, briefly specify in the supplementary remarks field.</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.MinimumEffectiveDose.InterferingSubstances</p>
<p>Remarks on result</p>	<ul style="list-style-type: none"> - not determinable - not determinable because of methodological limitations - not measured/tested - other: <p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free 	<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.MinimumEffectiveDose.RemarksOnResults</p>

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	<p>text explanation in the supplementary remarks field; or</p> <ul style="list-style-type: none"> - entering any remarks by selecting 'other:'. 	
Details on results	<p>RESULTS</p> <ul style="list-style-type: none"> - Effects observed: - Dose/concentration dependence of effects: - Begin and duration of effectiveness: - Observed effects in post-monitoring phase: - Reinvasion/reinfestation: - Existence of threshold concentration: - Other: <p>REPORTED STATISTICS:</p> <p>REFERENCE SUBSTANCE</p> <ul style="list-style-type: none"> - Results with reference substance: - Results with reference substance valid <p>Summarise any relevant results. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report, upload predefined table(s) in the rich text field 'Any other information on results incl. tables' or attach graphs in field 'Attached background material'.</p> <p>Note: Observed limitations on efficacy in terms of resistance,</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ResultsOnDetails</p>

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	undesirable or unintended side effects, or other limitations should be described in the corresponding fields below.	
Observed limitations on efficacy		ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy
Indication of resistance	<p>Indicate whether any development of resistance was observed or not. In below field 'Details on development of resistance', give details or provide any further explanation, e.g. stating that effects were observed, but considered negligible.</p> <p>Select 'not examined' or 'no data' as applicable.</p>	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.IndicationOfResistance
Details on development of resistance	<p>Provide details on the development of resistance as observed in the efficacy study(ies), including any evidence of cross-resistance.</p>	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.DetailsOnDevelopmentOfResistance
Undesirable or unintended side effects	<p>Indicate whether any undesirable or unintended side effects were observed or not. In below field 'Details on undesirable or unintended side effects', give details or provide any further explanation, e.g. stating that effects were observed, but considered negligible.</p> <p>Select 'not examined' or 'no data' as applicable.</p>	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.UndesirableOrUnintendedSideEffects

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<p>Details on undesirable or unintended side effects</p>	<p>Provide details on undesirable or unintended side effects as observed in the efficacy study(ies).</p> <p>Where appropriate or required by the relevant legislation, insert subheadings, e.g.:</p> <ul style="list-style-type: none"> -Adverse effects on plants - Adverse effects on health of host animals - Adverse effects on site of application (e.g. discoloration, corrosion, etc.) - Adverse effects on beneficial and other non-target organisms - Adverse effects on objects to be protected: 	<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.DetailsOnUndesirableOrUnintendedSideEffects</p>
<p>Other limitations observed</p>	<p>Where there is evidence of other possible limitations as derived from the study results, describe the relevant factors that can possibly reduce the efficacy, e.g. certain climatic or edaphic conditions.</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.OtherLimitationsObserved</p>
<p>Relevance of study results</p>	<p>For laboratory studies, provide arguments for performing such studies instead of a field test. If a study was conducted in a reduced scale, the dimension should be given as compared to the actual scale of the product (e.g. 'Test was reduced to a scale of 1:100').</p>	<p>ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.RelevanceOfStudyResults</p>

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	<p>If the study or studies summarised in this record were conducted with another formulation type or application method, provide a justification for this read-across through either the provision of a reasoned case based on data or through bridging arguments.</p> <p>Use freetext template and delete/add elements as appropriate.</p>	
Any other information on results incl. tables	Any other information on results incl. tables Block	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	ENDPOINT_STUDY_RECORD.EfficacyData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	ENDPOINT_STUDY_RECORD.EfficacyData.ApplicantSummaryAndConclusion

Links to support materials:

<https://www.julius-kuehn.de/en/jki-publication-series/bbch-scale/>

EPPO standard series PP1: Efficacy evaluation of plant protection products <https://pp1.eppo.int/>

EPPO global database: Scientific names and EPPO codes for target organisms

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7 Toxicological studies on the plant protection product

7.1 Acute toxicity – Endpoint summary

Purpose

Chemical (Active and Product): Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2):

- Rat LD50 oral
- Rat LD50 dermal
- Rat LC50 inhalation

Microorganism (Active and Product): Provide summary information of the most relevant study(-ies) in which the relative hazards associated with the different routes of exposure have been investigated in test mammals. The information generated through acute toxicity, pathogenicity and infectiveness testing is of particular value in assessing hazards likely to arise in accident situations and consumer risks due to exposure to possible residues.

All signs of infection and/or pathogenicity and a clearance assessment should be included.

The document should contain the information needed to be reported according to the list of end points for acute oral, dermal and inhalation toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.AcuteToxicity- v.6.2 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of toxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment
Acute toxicity: via oral route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityVi

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	be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.		aOralRoute.LinkToRelevantStudyRecords
Endpoint conclusion	<p>Endpoint conclusion block (quality of database)</p> <p>Note: In case of acute studies with micro-organisms, less severe but still adverse effects are also considered during the assessment. Dose descriptor: LD50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating dose, that should be chosen.</p>	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute.EndpointConclusion
Acute toxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP.</p>	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Note: In case of acute studies with micro-	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment

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	organisms, less severe but still adverse effects are also considered during the assessment. Dose descriptor: LC50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating concentration, that should be chosen.		ssment.AcuteToxicityViaInhalationRoute.EndpointConclusion
Physical form	Indicate in what physical form the test material was administered.	Open list	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.EndpointConclusion.PhysicalForm
Acute toxicity: via dermal route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP)	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion block (quality of database) Note: In case of acute studies with micro-organisms, less severe but still adverse effects	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute.EndpointConclusion

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	are also considered during the assessment. Dose descriptor: LD50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating dose, that should be chosen.		
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: Rat LD50 oral Rat LC50 inhalation Rat LD50 intraperitoneal/subcutaneous	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.Discussion
Justification for classification or non-classification	Not relevant for micro-organisms.	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.JustificationForClassificationOrNoClassification

7.1.1 Oral toxicity – Endpoint study record

Purpose

Chemical Active: The acute oral toxicity of the active substance shall always be reported

Chemical Product: A test for acute oral toxicity shall be carried out, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.

Microorganism Active: The acute oral toxicity study should permit the identification of effects following a single exposure to the microorganism, including an assessment of toxicity, pathogenicity and infectiveness, and evaluation of the clearance of the microorganism.

Microorganism Product: An acute oral test with the plant protection product shall always be carried out only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008.

ENDPOINT_STUDY_RECORD.AcuteToxicityOral - v.8.4 (Final) [September 2020]

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Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.DataSource
Materials and methods	<p>Material and methods – common block</p> <p>Applicable test guideline: Method B.1 bis Acute oral toxicity - fixed dose procedure (Annex to Regulation (EC) No 440/2008). Method B.1 tris Acute oral toxicity - Acute toxic class method (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 420: Acute oral toxicity: fixed dose procedure OECD Test Guideline 423: Acute oral toxicity: acute toxic class method OECD Test Guideline 425: Acute oral toxicity: up-and-down procedure Microbial Pesticide Test Guidelines: OPPTS 885.3050 Acute Oral Toxicity/Pathogenicity Are relevant for this endpoint Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.</p>	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods
Test type	<p>If possible, indicate whether the acute toxic class method, fixed dose procedure, up-and-down procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies. If neither of these test types applies, either leave field empty or use 'other':.</p> <p>Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.</p>	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.LimitTest
Test material	Test material	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestMaterials

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Test animals	<p>Test animals (OHT: Repeated dose toxicity)</p> <p>Species Select name of species. If not available from picklist, select 'other' and specify.</p> <p>NOTE: Human data should be reported in an appropriate subsection of section 'Basic information'</p> <p>It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.</p>	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on oral exposure	Indicate details of oral exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnOralExposure
Doses	Include the doses including unit administered to the test animals (in CFU/ml or CFU/kg bw). As appropriate include notes in parentheses, e.g. '(male)'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

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	table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the LD50 or other.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Verification that each enumeration method is sufficiently sensitive to serve as a useful quantitative assay, for the micro-organism in tissues, organs, and body fluids	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.Preliminary
Effect levels	Provide the LD50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. Where there are significant differences in response between the sexes, include the effect levels for both. If the test was conducted according to the fixed dose		ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels

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	<p>procedure, include the discriminating dose, i.e. the highest out of the four fixed dose levels which can be administered without causing compound-related mortality (including human kills).</p> <p>If no LD50 or other endpoint available from picklist is reported, but only a dose level, specify this dose using 'other' and indicate the effects observed in subfield 'Remarks on result'.</p>		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	<p>Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose procedure was used, select 'discriminating dose', i.e. the dose causing evident toxicity but not mortality. With the up-and-down procedure an 'approximate LD50' may be derived.</p> <p>Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 or LD50 <10. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.BasedOn

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	the test material specification. Select 'not specified' if the effect concentration type is not known.		
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	In the case of a fixed dose study, summarise evidence of toxicity and mortality of any preliminary sighting study at the fixed doses administered.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings. If the fixed dose method was used, indicate if animals appeared to recover completely and state if there were no obvious substance-related signs of toxicity.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight. . Indicate if body weight loss was greater than 10%.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.BodyWeight

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Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.GrossPathology
Other findings	The following should be reported for studies with micro-organisms: - Clearance estimates (numeration of the micro-organism/toxin in the relevant tissues/organs/body fluids at different time points) - Infectivity/persistence findings (numeration and findings in affected organs/tissues, if any)	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Attached document: Detailed results in the different dose groups can be reported in Appendix F format either as an attachment and in the 'Any other information on results incl. tables'	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.OverallRemarksAttachments
Applicants summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ApplicantSummaryAndConclusion

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7.1.2 Dermal toxicity– Endpoint study record

Purpose

Chemical Active: The acute dermal toxicity of the active substance shall be reported unless waiving is scientifically justified (for example where oral LD50 (2) is greater than 2 000 mg/kg). Both local and systemic effects shall be investigated.

Chemical Product: A test for dermal toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.

Microorganism Product: An acute percutaneous test with the plant protection product shall be conducted only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008, where applicable.

Findings of severe skin irritation (Grade 4 erythema or oedema) in the dermal study shall be used instead of performing a specific irritation study.

ENDPOINT_STUDY_RECORD.AcuteToxicityDermal - v.8.4 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: - Method B.3 Acute toxicity (dermal) (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 402: Acute Dermal Toxicity	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods
Test type	If possible, indicate whether the fixed dose procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies. If neither of these test types applies, either leave field empty or use 'other': Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestType

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Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.LimitTest
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestMaterials
Test animals	<p>Test animals (OHT: Repeated dose toxicity)</p> <p>Species: NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.</p> <p>Sex: Testing in one sex (usually females) is generally considered sufficient. Provide rationale for use of males (if applicable), in field 'Details on test animals and environment conditions'.</p>	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure
Type of coverage	Select type of coverage used. For robust study summaries specify the area of application in field 'Details on dermal exposure'.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.TypeOfCoverage
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on	Indicate details of exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsA

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dermal exposure			ndMethods.AdministrationExposure.DetailsofDermalExposure
Duration of exposure	Indicate total duration of exposure in hours, e.g. '4 hrs'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DurationOfExposure
Doses	<p>Include the doses including unit administered to the test animals, e.g. 50, 200, 1000 and 2000 mg/kg bw', or mention the doses after '- other:'. As appropriate include notes in parentheses, e.g. '(male)'.</p> <p>For a robust study summary also indicate the analytical concentrations of the test substance in the vehicle in the results table (see field 'Mortality').</p>	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	<p>Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	<p>Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate. If TG 402 (9 October 2017) was used, see flowchart for the testing procedure in its Annex 2.</p>	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsofStudyDesign
Statistics	Indicate the method of calculating the LD50 or other, if applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.Administr

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			ationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.Preliminary
Effect levels			ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose procedure was used, select 'discriminating dose', i.e the dose causing evident toxicity but not mortality. With the up-and-down procedure an 'approximate LD50' may be derived. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 mg/kg bw or LD50 <10 mg/kg bw. An additional explanation may be given in field	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.Endpoint

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	'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. For GHS classification, see 'Interpretation of results' under section 'Applicant's summary conclusion' below.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results where required and in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If the fixed dose method was used, tabulate the evidence of toxicity and mortality (number of animals) for each sex	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.Mortality

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	and dose group. 'Evidence of toxicity' describes clear signs of toxicity following administration of test substance, which should be such that an increase in the exposure concentration can be expected to result in the development of severe toxic signs and probable mortality. Note: Specific tables may be required.		
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Distinguish between effects at the site of application (local) and systemic effects. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ApplicantSummaryAndConclusion
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7.1.3 Inhalation toxicity - Endpoint study record

<p>Purpose: Chemical: The acute inhalation toxicity of the active substance shall be reported where any of the following apply:</p> <ul style="list-style-type: none"> - the active substance has a vapour pressure $> 1 \times 10^{-2}$ Pa at 20 °C; - the active substance is a powder containing a significant proportion of particles of a diameter $< 50 \mu\text{m}$ ($> 1\%$ on weight basis); - the active substance is included in products that are powders or are applied by spraying. <p>The head/nose only exposure shall be used, unless whole body exposure can be justified.</p> <p>Microorganism Active: The acute toxicity study by inhalation should permit the identification of effects following a single exposure to the microorganism, including an assessment of toxicity, pathogenicity and infectiveness, and evaluation of the clearance of the microorganism.</p> <p>Microorganism Product: The acute inhalation toxicity study must be carried out where the plant protection product:</p> <ul style="list-style-type: none"> - is used with fogging equipment, - is an aerosol, - is a powder containing a significant proportion of particles of diameter < 50 micrometre ($> 1\%$ on a weight basis), - is to be applied from aircraft in cases where inhalation exposure is relevant, - is to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 micrometre ($> 1\%$ on a weight basis), - contains a volatile component at greater than 10%.
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ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation - v.9.4 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Microbial Pesticide Test Guidelines: OPPTS 885.3150 Acute Pulmonary Toxicity/Pathogenicity Are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods

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Test type	If possible, indicate which method was used in the study. If neither of these test types applies, either leave field empty or use 'other:'. Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Close d list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.LimitTest
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.TestMaterials
Test animals	Select name of species. If not available from picklist, select 'other' and specify. NOTE: Human data should be reported in an appropriate subsection of section 'Basic information'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure. Sex: Provide rationale for use of females (if applicable), in field 'Details on test animals and environment conditions'.	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure
Route of administration	Specify the route of administration by indicating in what physical form the test material was administered. In case of intratracheal administration, specify it under 'Type of inhalation'.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure	Indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield. In case of intratracheal administration, select other and report this in the 'remarks' field.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposure

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Vehicle	Select the vehicle used. If not available from picklist, select 'other'.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. This field can be used for giving an additional information by selecting 'other:' or selecting a pre-defined reason why no numeric value is provided, e.g. 'not measured/tested' or 'not determinable' and entering free text explanation in the supplementary remarks field.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remark on MMAD/GSD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on inhalation exposure	Indicate details of inhalation exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt (i.e. diagram as pdf/jpeg etc.) from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnInhalationExposure
Analytical verification of test atmosphere concentrations	Indicate whether the test atmosphere concentrations and the particle size were analytically verified. For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. If any problems occurred, then they should be reported in more detail. If this could have affected the	Close list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfTestAtmosphereConcentrations

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	veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.		
Duration of exposure	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DurationOfExposure
Remarks on duration	Enter any remarks related to the recorded value as appropriate.	Text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnDuration
Concentrations	Provide rationale for the selection of the starting concentration. Include the nominal concentrations the test animals were exposed to, e.g. '100, 500, 2500 and 20000 ppmV(gas)' or '0.5, 2.0, 10, 20 mg/L air (dust/mist)'. For micro-organisms (CFU/L air or some other units should be used) As appropriate include notes in parentheses, e.g. '(male)'. For robust study summaries, also provide the analytical concentrations in the results table (see field 'Mortality').	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Concentrations
No. of animals per sex per dose	Enter number or state numbers for different groups if varying, e.g. '10 (controls), 5 (in test groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMet

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	other examinations performed. Use freetext template and delete/add elements as appropriate.		hods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the category. LC50 or other, if applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Information on the test atmosphere characteristics can be provided e.g. Nominal concentration and Temperature For microorganisms: Verification that each enumeration method is sufficiently sensitive to serve as a useful quantitative assay for the MPCA tissues, organs, and body fluids should be reported	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study (if performed).	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.Preliminary
Effect levels	Provide the LC50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. Where there are significant differences in response between the sexes, include the effect levels for both. If no LC50 or other endpoint available from picklist is reported, but only a concentration level, specify this concentration using 'other' and indicate the effects observed in subfield 'Remarks on result'.		ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment.	Checkbox	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Close list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.Sex

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Dose descriptor	<p>Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose concentration was used, select 'discriminating conc.', i.e. the dose causing evident toxicity but not mortality.</p> <p>Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LC50 >10 mg/m³ air or LC50 <10 mg/m³ air.</p> <p>For micro-organisms (CFU/L air or some other units should be used)</p> <p>An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.Endpoint
Effect level	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	<p>Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification.</p> <p>Select 'not specified' if the effect concentration type is not known.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.BaseOn
95% CL	<p>For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if relevant available.</p> <p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.cl
Exp. duration	<p>Enter numeric value. If exposure cannot be described by a single (integer) number, calculate hours and</p>	Unit measure	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion

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	minutes reported to a decimal number, preferably based on the unit 'h (hour)', e.g. 4.15 h for 4 h, 9 min.	with Closed List (Decimal)	ssion.EffectLevels.ExposureDuration
Remarks on result	This field can be used for: - giving a qualitative description of results where required and in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.Mortality
Clinical signs	Choose the corresponding clinical sign and briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. (For non TG 433 inhalation studies, do not dwell on effects that are most likely due to agonal death.) Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. If another clinical sign should be reported, choose option – other: and mention the sign as contained in the comprehensive Clinical sign lexicon provided as Table 2 in the publication by Sewell F. et al. (2015), "A global initiative to refine acute inhalation studies through the use of 'evident toxicity' as and endpoint: Towards adoption of the Fixed Concentration Procedure", Regul Toxicol Pharmacol, Vol. 73, pp. 770-779. Note if there was a reference point (e.g. NOAELs) for clinical findings.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight. Indicate if body weight loss was greater than 10%.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInh

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			ation.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.GrossPathology
Other findings	For microorganism studies report results related to: - Clearance estimates, notably in the lungs (numeration of the micro-organism/toxin in the relevant tissues/organs/body fluids at different time points) - Infectivity/persistence findings (numeration of micro-organism and findings in affected organs/tissues, if any)	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummaryAndConclusion
Executive summary		Rich text area	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummaryAndConclusion.ExecutiveSummary

7.1.4 Irritation – Endpoint summary

Purpose

Chemical and Microorganism: Indicate whether Skin irritation, Eye irritation is observed.

The document should contain the information needed to be reported according to the list of end points for skin and eye irritation (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.IrritationCorrosion - v.5.0 (Final) [July 2020]

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Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of irritation studies and effects	Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment
Skin irritation / corrosion		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP).	Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.EndpointConclusion
Endpoint conclusion	“Adverse effect observed (irritating)” should be chosen if the substance meets the classification criteria for skin irritation (Category 2).	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.EndpointConclusion.EndpointConclusion

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	<p>“Adverse effect observed (corrosive)” should be chosen if the substance meets the classification criteria for skin corrosion (Categories 1A, 1B or 1C).</p> <p>“No adverse effect observed (not irritating)” should be chosen if the substance does not meet the criteria for classification.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p>		
Eye irritation		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP).</p>	Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.EndpointConclusion
Endpoint conclusion	<p>“Adverse effect observed (irritating)” should be chosen if the substance meets the</p>	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirati

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	<p>classification criteria for eye irritation (Category 2). "Adverse effect observed (irreversible damage)" should be chosen if the substance meets the classification criteria for irreversible effects on the eye (Category 1). "No adverse effect observed (not irritating)" should be chosen if the substance does not meet the criteria for classification. If "No study available" is chosen, a justification needs to be provided.</p>		<p>onIrritation.EndpointConclusion.EndpointConclusion</p>
Respiratory irritation		Header 2	<p>ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation</p>
Endpoint conclusion		Header 3	<p>ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion</p>
Endpoint conclusion	<p>"Adverse effect observed (irritating)" should be chosen if the substance is found to cause respiratory irritation. "Adverse effect observed (irreversible damage)" should be chosen if the substance does not cause respiratory irritation. "No study available" should be chosen if</p>	Closed list	<p>ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion.EndpointConclusion</p>

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	there is no data to conclude on respiratory irritation.		
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: skin/eye irritant or non-irritant	Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.IrritationCorrosion.JustificationForClassificationOrNonClassification.Remarks

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7.1.4.1 Skin irritation – Endpoint study record

Purpose

Chemical (Active): Provide information on the potential for skin irritancy of the active substance including, where relevant, the potential reversibility of the effects observed.

Before undertaking in vivo studies for corrosion/irritation of the active substance, a weight-of-evidence analysis shall be performed on the existing relevant data. Where insufficient data are available, they can be developed through application of sequential testing.

The testing strategy shall follow a tiered approach: (1) the assessment of dermal corrosivity using a validated in vitro test method; (2) the assessment of dermal irritation using a validated in vitro test method (such as human reconstituted skin models); (3) an initial in vivo dermal irritation study using one animal, and where no adverse effects are noted; (4) confirmatory testing using one or two additional animals.

Chemical (Product): The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008, for which skin irritation properties of all components shall be provided or reliably predicted with a validated method.

Microorganism (Product): The skin irritancy of the plant protection product, including the potential reversibility of the effects observed, must always be determined where the co-formulants are not expected to be skin irritant or the microorganism is shown not to be skin irritant or where it is likely, as indicated in the test guideline, that severe skin effects can be excluded.

ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion - v.8.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.DataSource
Materials and methods	<p>Material and methods – common block</p> <p>Applicable test guideline: Method B.4 Acute toxicity: dermal irritation/corrosion (Annex to Regulation (EC) No 440/2008).</p> <p>OECD TG 430 / Method B.40 In vitro skin corrosion: transcutaneous electrical resistance test (TER) (Annex to Regulation (EC) No 440/2008).</p>	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods

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	<p>OECD TG 431 / Method B.40 bis In vitro skin corrosion: human skin model test (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 404: Acute Dermal Irritation/Corrosion</p> <p>OECD Test Guideline 431: In vitro Skin Corrosion: Human Skin Model Test</p> <p>OECD Test Guideline 430: In vitro Skin Corrosion: Transcutaneous Electrical Resistance Test</p> <p>OECD Test Guideline 435: In vitro Membrane Barrier Test Method for Skin Corrosion</p> <p>OECD Test Guideline 439: In vitro Skin Irritation: Reconstructed Human Epidermis Test Method</p> <p>OECD TG 439 / Method B.46 In vitro skin irritation: reconstructed human epidermis model test (Annex III of Regulation (EC) No 761/2009 (7).</p>		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestMaterials
In vitro test system		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem
Test system	Select as appropriate. If not available from picklist, select 'other:' and specify. Further information can be given in the supplementary remarks field. Use of other than the test systems recommended by the test guidelines is to be considered as deviation from guideline and should be noted and justified in the field "Test guideline - Deviations".	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.TestSystem
Source species	Select as appropriate. Indicate the species used as source of the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.SourceSpecies
Cell type	For in vitro tests, e.g. according to OECD Guidelines 431 and 439, indicate the cell type used to construct the in	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAnd

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	vitro test system. If not available from picklist, select 'other:' and specify.		Methods.InVitroTestSystem.CellType
Cell source	For in vitro tests, e.g. according to OECD Guidelines 431 and 439, indicate the source of the cells used to construct the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.CellSource
Source strain	For in vitro tests, e.g. according to OECD Guideline 430, indicate the strain used as source of the test system. If not available from picklist, select 'other:' and specify. Use of other than the strain recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.SourceStrain
Details on animal used as source of test system	For in vitro tests, e.g. according to OECD Guideline 430, give details on the animal used as source of the skin discs. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DetailsOnAnimalUsedAsSourceOfTestSystem
Justification for test system used	Provide a justification for the test system used	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.JustificationForTestSystemUsed
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.Vehicle
Details on test system	For in vitro tests, e.g. according to OECD Guidelines 430, 431, 435 or 439, indicate details on the test system used including test conditions. Select freetext template for the respective type of study (i.e. Transcutaneous electrical resistance test (TER) (e.g OECD TG 430) or Artificial membrane barrier test method (e.g OECD TG 435) or Human skin model test (e.g OECD TG 431) or Reconstructed human epidermis test method) (e.g OECD	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DetailsOnTestSystem

	<p>TG 439)) and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Explanations:</p> <ul style="list-style-type: none"> - SKIN DISC PREPARATION (if Transcutaneous electrical resistance test): Summarise the procedure used to prepare the skin discs and, for each animal skin used as source for skin discs, indicate the electrical resistances obtained with two of the isolated skin discs before testing (should be $\geq 10 \text{ k}\Omega$) - RECONSTRUCTED HUMAN EPIDERMIS (RHE) TISSUE: For human skin model tests, e.g. according to OECD Guidelines 431 and 439, indicate the Reconstructed human Epidermis (RhE) tissue model used, batch number(s) used, the production date, the shipping date, the delivery date, and the date of initiation of testing. - TEMPERATURE USED FOR TEST SYSTEM: Indicate the temperature used during treatment / exposure (e.g. room temperature, 25°C, 37°C, etc). If more than one temperature was used, indicate the different sequential temperatures used and the exact exposure time at each temperature. - REMOVAL OF TEST MATERIAL AND CONTROLS: Indicate the volume (if applicable) and number of washing steps used to remove the test item from the test system after treatment / exposure. Indicate if any observable damage was induced by the washing procedure. Indicate any modification to the validated SOP introduced in the washing procedure. - FUNCTIONAL MODEL CONDITIONS WITH REFERENCE TO HISTORICAL DATA (if human skin model test): Provide details on viability (negative control OD values of each tissue batch in comparison to historical acceptability ranges); barrier function (for each tissue batch, indicate the IC50 obtained with 18 h treatment with SDS or the ET50 obtained with treatment with 1% Triton X-100 in comparison to historical acceptability ranges); morphology (number and type of viable epithelial cell layers (basal layer, stratum spinosum, stratum granulosum) and the approximate number of layers of the stratum corneum, as assessed by histological examination); contamination (indicate if the tissue batches used were free of contamination by bacteria, viruses, mycoplasma or fungi, reproducibility (indicate the reproducibility of the negative and positive 	
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	controls over time) - PREDICTION MODEL / DECISION CRITERIA: Describe and justify the prediction model / decision criteria used to derive the corrosion/irritation classification		
Control samples	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information. Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control, a concurrent negative control, non-specific colour controls and non-specific MTT reduction controls.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.ControlSamples
Amount/ concentration applied	Give the amount(s) of substance / controls applied (volume or weight with unit) and the concentration of the substance, controls and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.AmountConcentrationApplied
Duration of treatment / exposure	Indicate length of time test material was in contact with test system, e.g. '3 min. ' or '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DurationOfTreatmentExposure
Duration of post-treatment incubation (if applicable)	Indicate length of post-treatment incubation period as applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DurationOfPostTreatmentIncubationIfApplicable
Number of replicates	Indicate the number of replicate tissues/skin discs used in each treatment / exposure and control groups.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.NumberOfReplicates
Test animals	Test animals (OHT: Repeated dose toxicity) Species: For in vitro tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify.	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestAnimals

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	Use of other than the species recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in section 'Skin irritation / corrosion', that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.		
Test system		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem
Type of coverage	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.TypeOfCoverage
Preparation of test site	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.PreparationOfTestSite
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.Vehicle
Controls	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information). Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control and a concurrent negative control.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.Controls
Amount / concentration applied	Give the amount(s) of substance applied (volume or weight with unit) and the concentration of the substance and vehicle (if used) in the test solution. Specify if	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.

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	different doses were applied. Use freetext template and delete/add elements as appropriate.		AmountConcentration Applied
Duration of treatment / exposure	Indicate length of time test material was in contact with test animal, including unit, e.g. '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_RECORDER.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.DurationOfTreatmentExposure
Observation period	Indicate length of observation period.	Multi-line text	ENDPOINT_STUDY_RECORDER.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.ObservationPeriod
Number of animals	Indicate number of animals used.	Multi-line text	ENDPOINT_STUDY_RECORDER.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.NumberOfAnimals
Details on study design	For in vivo tests, e.g. according to OECD Guideline 404, give details on study design. Describe the method of calculation of maximum average score given in the results table used (if applicable). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORDER.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.DetailsOnStudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORDER.SkinIrritationCorrosion.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORDER.SkinIrritationCorrosion.ResultsAndDiscussion
In vitro		Header 2	ENDPOINT_STUDY_RECORDER.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro
Results	Indicate the overall irritation / corrosion results for the test substance in terms of tissue viability, transcutaneous electrical resistance, penetration time or		ENDPOINT_STUDY_RECORDER.SkinIrritationCorrosion.ResultsAndDi

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	<p>other. Copy this block of fields as appropriate.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables".</p> <p>(Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'In vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.</p> <p>Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		discussion.InVitro.Results
Irritation / corrosion parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field, e.g. "based on optical density measurement".	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.IrritationCorrosionParameter
Run / experiment	Indicate the run / experiment the measurement relates to, if more than one run / experiment was performed and the length of time the test material was in contact with the test system, if different exposure time periods were applied in different test runs of this study. Examples: Run 1 (duration of exposure: 2 hours); Run 1, replicate 1 (duration of exposure: 2 hours), Mean of three runs with two replicates each.	Text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.RunExperiment
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.Value
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. without test substance, with/without solvent) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) is valid, i.e. substance(s) with known lack of irritation/corrosion in	Open list with	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDi

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	the test conducted. Relevant remarks can be given in the supplementary remarks field.	remarks	discussion.InVitro.Results.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) is valid, i.e. substance(s) with known irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.RemarksOnResults
Results			
Other effects / acceptance of results	Use freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system, no visible damage on test system, direct-MTT reduction, colour interference with MTT, etc). Discuss the applicability of the test method to test colorants and/or direct MTT-reducers in reference to the %NSC and/or %NSMTT values reported in the block of fields above. - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative control, positive control, and variability between replicate measurements) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.OtherEffectsAcceptanceOfResults

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In vivo		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo
Results	<p>For in vivo test results, provide individual time point scores per animal and mean scores. If reported or required by the relevant legislation, indicate overall irritation / corrosion results in terms of an Overall irritation score, Primary dermal irritation index or other (specify). Copy this block of fields as appropriate. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'In vivo, depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables".</p> <p>Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results
Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Parameter
Basis	Indicate if the score is the mean of all scoring results for the parameter selected on the preceding subfield or based on individual animals, e.g. animal #1. Option 'animal:' allows to enter text/numbers in the related supplementary remarks field, e.g. 'animal: #1, 2 and 3').	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Basis
Time point	Indicate the time point(s) the score relates to by selecting the appropriate value from the picklist, e.g. '24' or '24/48/72 h' (if the same score applies), and in the following field, the unit.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.TimePoint
Score	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a	Range	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDi

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	range use both numeric fields together with the appropriate qualifier(s) if applicable.	(Decimal)	scussion.InVivo.Results.Score
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Scale
Reversibility	Indicate whether the irritation was reversible or not. As appropriate use supplementary remarks field linked to the picklist item selected for indicating average time for (non-)reversibility.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Reversibility
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.RemarksOnResults
Results			
Irritant / corrosive response data	For robust study summaries or as requested by the regulatory programme, tabulate the raw data for each individual animal at each observation time up to removal of each animal from the test (unless these data are given in above block of fields 'Irritation / corrosion results'). Upload predefined table(s) if any in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). In field "Details on study design (in vivo)", describe the method of calculation used. Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.IrritationCorrosionResponseData
Other effects	Use freetext template and delete/add elements as appropriate. For in vivo tests, e.g. according to OECD Guideline 404, describe any other adverse local (e.g. defatting of skin) and systemic effects in addition to dermal irritation or corrosion.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.OtherEffects

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Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ApplicantSummaryAndConclusion

7.1.4.2 Eye irritation – Endpoint study record

Purpose

Chemical: The eye irritancy of the active substance shall always be tested, except where it is likely that severe effects on the eyes may be produced based on criteria listed in the test methods. The results of the study shall provide the potential of eye irritancy of the active substance including, where relevant, the potential reversibility of the effects observed. Before undertaking in vivo studies for eye corrosion/irritation of the active substance, a weight-of-evidence analysis shall be performed on the existing relevant data.

Where available data are considered insufficient, further data may be developed through application of sequential testing. The testing strategy shall follow a tiered approach:

- (1) the use of an in vitro dermal irritation/corrosion test to predict eye irritation/corrosion;
- (2) the performance of a validated or accepted in vitro eye irritation study to identify severe eye irritants/corrosives (such as Bovine Corneal Opacity and Permeability (BCOP) assay, Isolated Chicken Eye (ICE) assay, Isolated Rabbit Eye (IRE) assay, Hen's Egg Test - Chorio-Allantoic Membrane assay (HET-CAM)), and where negative results are obtained, the assessment of eye irritation using an in vitro test method for identification of non irritants or irritants, and where not available;
- (3) an initial in vivo eye irritation study using one animal, and where no adverse effects are noted;
- (4) confirmatory testing using one or two additional animals.

Microorganism (product): The test will provide the potential for eye irritation of the plant protection product, including the potential reversibility of the effects observed. The eye irritancy of the plant protection product must be determined, where the co-formulants are suspected to be eye irritant, except where the microorganism is eye irritant or where it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.

ENDPOINT_STUDY_RECORD.EyeIrritation - v.8.3 (Final) [September 2020]

Name	Instructions	Type	Field Path
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Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.5 Acute toxicity: eye irritation/corrosion OECD 405 OECD 437 OECD 438 Method B.47 Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants (Method B.48 Isolated chicken eye test method for identifying ocular corrosives and severe irritants	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestMaterials
Test animals / tissue source		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals
Species	Select as appropriate. For in vitro / ex vivo tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify. Use of other than the species recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in section 'Irritation / corrosion', that human data are provided by creating a record and referring to the human data in block 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.	Open list	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.Species

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Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.Strain
Details on test animals or tissues and environmental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - Food quality and water quality: provide analytical information on the nutrient and dietary contaminant levels. Similarly provide analytical information on the drinking water used in the study. - IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing).	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.OrganismDetails
Test system		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.Vehicle
Controls	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information. Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control and a concurrent negative control.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.Controls
Amount / concentration applied	Give the amount(s) of substance / controls applied (volume or weight with unit) and the concentration of the substance, controls and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.AmountConcentrationApplied

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Duration of treatment / exposure	Indicate length of time test material was in contact with animal/cell/tissue including unit, e.g. '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DurationOfTreatmentExposure
Observation period (in vivo)	Indicate length of observation period.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.ObservationPeriod
Duration of post-treatment incubation (in vitro)	Indicate length of post-treatment incubation period as appropriate.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DurationOfPostTreatmentIncubationInVitro
Number of animals or in vitro replicates	Indicate number of animals used (if in vivo) or, in the case of in vitro tests, the number of replicate tissues used in each treatment / exposure and control group.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.NumberOfAnimals
Details on study design	Select freetext template for the respective type of study (i.e. In vivo test method, In vitro test method (BCOP) or In vitro test method (ICE) and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DetailsOnStudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion
In vitro		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro

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Results	<p>Indicate the overall irritation / corrosion results for the test substance in terms of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). Copy this block of fields for reporting several scores, e.g. means of individual replicates.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables".</p> <p>(Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'in vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.</p> <p>Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy
Irritation parameter	<p>Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. For instance, in the case of morphological effects, specify if and to what severity pitting of corneal epithelial cells, loosening of epithelium, roughening of the corneal surface and sticking of the test substance to the cornea occurred.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.IrritationParameter
Run / experiment	<p>Indicate the run / experiment the measurement relates to, if more than one run / experiment was performed and the length of time the test material was in contact with the test system, if different exposure time periods were applied in different test runs of this study. Examples: Run 1 (duration of exposure: 10 min.); Run 1, replicate 1 (duration of exposure: 10 min.), Mean of three runs with two replicates each.</p>	Text	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.RunExperiment
Value	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range (Decimal)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.Value

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Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. vehicle only without test substance) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) demonstrated lack of irritation/corrosion of the known non-irritant/non-corrosive substance, and/or that the negative control falls within the acceptance criteria range as described in the TG. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) demonstrated irritation/corrosive effects of the known irritant/corrosive substance and/or that positive control results fall within the acceptance criteria as described in the TG. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.RemarksOnResult
Results			
Other effects / acceptance of results	Select freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system) - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative and positive control) were met in reference to historical ranges. Indicate the range of historical values if	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.OtherEffectsAcceptanceOfResults

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	different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
In vivo		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo
Results	Indicate the scores of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). In subfield "Basis of irritation parameter" indicate if the score is an average value (i.e. mean), or for a give animal, or other. Copy this block of fields for reporting several scores, e.g. means or for individual animals. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'in vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults
Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Parameter
Basis	Indicate if the score is the mean of all scoring results for the parameter selected on the preceding subfield or based on individual animals, e.g. animal #1. Option 'animal:' allows to enter text/numbers in the related supplementary remarks field, e.g. 'animal: #1, 2 and 3').	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Basis

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Time point	Indicate the time point(s) the score relates to by selecting the appropriate value from the picklist, e.g. '24' or '24/48/72 h' (if the same score applies), and in the following field, the unit.	Open list	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.TimePoint
Score	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Score
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Scale
Reversibility	Indicate whether the irritation was reversible or not. As appropriate use supplementary remarks field linked to the picklist item selected for indicating average time for (non-)reversibility.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Reversibility
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.RemarksOnResults
Results			
Irritant / corrosive response data	For robust study summaries or as requested by the regulatory programme, tabulate the raw data for each individual animal at each observation time (unless these data are given in above block of fields 'Irritation / corrosion results'). Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Describe the method of calculation of maximum average score given in the results table. Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResponseData

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Other effects	Select freetext template and delete/add elements as appropriate. Describe any other relevant results including lesions and clinical observations, ophthalmoscopic and histopathological findings, effects of rinsing or washing if applicable.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.OtherEffects
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.OverallRemarksAttachments
Applicants' summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.ApplicantSummaryAndConclusion

7.1.5 Skin sensitisation - Endpoint summary

<p>Purpose: Chemical (Active) - Microorganism (Product): Provide summary information of the most relevant study(ies) from which the key value for active substance assessment is extrapolated. Provide only the most relevant details e.g. Sensitising (state method, e.g. LLNA) related to the potential of the chemical active or microorganism product to provoke sensitisation.</p> <p>Microorganism (Active): The available methods for testing dermal sensitisation are not suitable for testing microorganisms, and there are no validated test methods for sensitisation by inhalation. As a consequence, all microorganisms will be labelled as potential sensitisers, unless the applicant wants to demonstrate the non-sensitising potential by submitting data. Therefore, this data requirement should be regarded as optional, on a provisional basis.</p> <p>The document should contain the information needed to be reported according to the list of end points for skin sensitisation (SANCO/12592/2012-rev. 2, 22 March 2019).</p>

ENDPOINT_SUMMARY.Sensitisation - v.4.0 (Final) [April 2019]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.Sensitisation.AdministrativeDataSummary

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	Description of key information: Provide a brief description of the study and the potential of the micro-organism to provoke sensitisation reactions.		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment
Skin sensitisation		Header 2	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (sensitising)" should be chosen if the micro-organism shows effects of skin sensitisation . "No adverse effect observed (not sensitising)" should be chosen if the substance does not show effects of skin sensitisation. If "No study available"	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.EndpointConclusion

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	is chosen, a justification needs to be provided.		
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.AdditionalInformation
Respiratory sensitisation		Header 2	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected:</p> <ul style="list-style-type: none"> quality of the study (e.g. Klimisch score, duration of the study, 	Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.LinkToRelevantStudyRecords

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	whether or not the study is GLP.		
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion
Endpoint conclusion	<p>"Adverse effect observed (sensitising)" should be chosen if the micro-organism shows effects of respiratory sensitisation.</p> <p>"No adverse effect observed (not sensitising)" should be chosen if the substance does not show effects of respiratory sensitisation.</p> <p>If "No study available" is chosen, a justification needs to be provided.</p>	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion.EndpointConclusion
Additional information	Provide additional information related to the endpoint, for example: sensitising (state source of evidence, e.g. type of study, clinical data, etc)	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion.AdditionalInformation
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Sensitisation.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Sensitisation.JustificationForClassificationOrNonClassification.Remarks

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7.1.5 Skin sensitization - Endpoint study record

Purpose:

Chemical (Active): Provide sufficient information to assess the potential of the active substance to provoke skin sensitisation reactions. The study shall always be carried out, except where the active substance is a known sensitiser. The local lymph node assay (LLNA) shall be used, including where appropriate the reduced variant of the assay. In case the LLNA cannot be conducted, a justification shall be provided and the Guinea Pig Maximisation Test shall be performed. Where a guinea pig assay (Maximisation or Buehler), meeting OECD guidelines and providing a clear result, is available, further testing shall not be carried out for animal welfare reasons. Since an active substance identified as a skin sensitiser can potentially induce hypersensitivity reaction, potential respiratory sensitisation should be taken into account when appropriate tests are available or when there are indications of respiratory sensitisation effects. Note: the sections of this document to be completed are dependent on the endpoint selected

Chemical (Product): The skin sensitisation test shall be carried out unless the active substances or co-formulants are known to have sensitising properties or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin sensitisation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the sensitising potential of the total mixture.

Microorganisms (Active): Provide sufficient information to assess the potential of the microorganism to provoke sensitisation reactions by inhalation as well as with dermal exposure. A maximised test has to be performed.

Microorganism (Product): The test will provide sufficient information to assess the potential of the plant protection product to provoke skin sensitisation reactions. The test must be carried out where the co-formulants are suspected to have skin sensitising properties, except where the microorganism(s) or the co-formulants are known to have skin sensitising properties.

ENDPOINT_STUDY_RECORD.SkinSensitisation - v.10.5 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 406 Method B.42 Skin sensitisation: Local lymph node assay (Annex to Regulation (EC) No 440/2008). Method B.6 Skin sensitisation (Annex to Regulation (EC) No 440/2008).	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods

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	OECD 429 OECD 442A + 442B.		
Type of study	Select type of study as appropriate. If another than the LLNA test system was used, a justification may be required in the following field.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.TypeOfStudy
Justification for non-LLNA method	Provide a justification for the use of another than the LLNA test system (if in vivo), if the relevant legislation so requires. For instance it could be argued that the LLNA method was not available yet by the time the study was conducted or that the LLNA test is not suitable for that substance or that an appropriate guinea pig maximisation test is available which would not justify conducting an additional LLNA due to animal welfare. Refer to the relevant legislation-specific guidance document.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.JustificationForNonLLNAMethod
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.TestMaterials
In vitro test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem
Details of test system	If standard cell lines not used, please select 'other:' and specify in the freetext field exact details of the cell line used.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.DetailsTestSystem
Details on the study design	PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used (EC/CAS, purity, treatment of the material) etc. If stable dispersion is not obtained and the test solution is still used, add an explanation why this is not considered to affect the validity of the study. DOSE RANGE FINDING ASSAY: describe the highest concentration used for the dose range finding assay and how appropriate doses were selected taking solubility and cytotoxicity into account. Specify which solvents were used and finally selected and how cytotoxicity assessment was performed. APPLICATION OF THE TEST CHEMICAL AND CONTROL SUBSTANCES: describe the application of test chemical	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.DetailsOnStudyDesign

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	<p>and control substance exposure conditions in detail. SEEDING AND INCUBATION: describe the seeding and incubation conditions and whether precipitation was noted. MEASUREMENT OF CELL SURFACE EXPRESSION/LUCIFERASE ACTIVITY: describe the steps taken to ensure the suitability of the cell surface marker expression/luciferase activity measurements for the test chemical, including solvents used LUCIFERASE ACTIVITY MEASUREMENTS: describe the steps taken to ensure the suitability of the luciferase activity measurements for the test chemical, including solvents used DATA EVALUATION: report the cytotoxicity measurements taken and the prediction model to be used.</p>		
Vehicle / solvent control	Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.VehicleSolventControl
Negative control	Select the negative control as appropriate. If no negative control required (Keratinosens), select 'not applicable'. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.NegativeControl
Positive control	Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard positive control.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.PositiveControl
In chemico test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem
Details of test system	Indicate the purity of the peptides used in the 'remarks' field. If standard peptides are not used, please select 'other:' and specify in the freetext field the exact details of the peptide used and supporting information on the scientific validity of their use.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.DetailsTestSystem
Details on the study design	PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used (EC/CAS, purity, treatment of the	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I

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	<p>material) etc. INCUBATION: describe the incubation conditions and whether precipitation was noted. PREPARATION OF THE HPLC: describe the steps taken to ensure the suitability of the HPLC for the test chemical, including solvents used DATA EVALUATION: report the UV wavelength used for peptide/derivative detection.</p>		nChemicoTestSystem.DetailsOnStudyDesign
Vehicle / solvent	Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.VehicleSolvent
Positive control	Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard positive control.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.PositiveControl
In vivo test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem
Test animals		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals
Species	<p>Select as appropriate. For in vitro tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify. NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Sensitisation data'.</p> <p>It can be useful to document, in section 'Skin sensitisation', that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.</p>	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify. In the supplementary remarks field, also specify the substrain if not specified by picklist item. Provide rationale for choice of strain and substrain if deviating from the ones recommended by the test guideline used.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Strain

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Sex	Select as appropriate. If females were used, indicate in field "Details on test animals and environmental conditions" whether nulliparous and non-pregnant.	Close d list	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.TestA nimals.Sex
Details on test animals and environmental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing).	Text templ ate	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.TestA nimals.DetailsOnTestA nimalsAndEnvironment alConditions
Study design: in vivo (non-LLNA)		Head er 3	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA
Induction	Record the vehicle, test substance concentrations used for induction exposure(s), the total amount of substance applied and the day(s) and duration of the induction. Copy this block of fields as appropriate.		ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA. Induction
Route	Indicate the route of induction exposure.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA. Induction.Route
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided.	Open list with rema rks	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA. Induction.Vehicle
Concentration / amount	Provide the test substance concentrations used for induction exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA, mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted).	Multi- line text	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA.

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			Induction.ConcentrationAmount
Day(s)/duration	Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8).	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Induction.DaySDuration
Adequacy of induction	Indicate if the test concentration used for the induction exposure was well-tolerated systemically and the highest to cause mild-to-moderate skin irritation, or if the highest technically applicable concentration used. If the substance is a non-irritant, indicate in field 'Details on study design' the appropriate pre-treatment applied for causing local irritation.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Induction.AdequacyOfInduction
Induction Challenge			
Challenge	Record the vehicle, test substance concentrations used for challenge exposure(s), the total amount of substance applied and the day(s) and duration of challenge. Copy this block of fields as appropriate. Consecutive numbers can be entered in the subfield "No." for indicating multiple challenges.		ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge
No.	For indicating multiple challenges or rechallenge select a consecutive number from drop-down list.	Close list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.No
Route	Indicate the route of challenge exposure.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.Route
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.Vehicle
Concentration / amount	Provide the test substance concentrations used for challenge exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA,	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.Study

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	mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted).		DesignInVivoNonLLNA.Challenge.ConcentrationAmount
Day(s)/duration	Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8).	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.DaySDuration
Adequacy of challenge	Indicate if the test concentration used for the challenge exposure was the highest non-irritation dose.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.AdequacyOfChallenge
Challenge			
No. of animals per dose	Provide number of animals per dose or range if different numbers were used, e.g. '10 (controls), 10-20 (in test groups)'.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.NoOfAnimalsPerDose
Details on study design	For in vivo non-LLNA sensitisation tests, describe any range finding tests (pilot study) and for the main study the induction and challenge procedures including the type of information given in the freetext template. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Example for Freund's Complete Adjuvant (FCA) test (partly adopted from OECD 406): - A. INDUCTION EXPOSURE - No. of exposures: 5 - Exposure period: - - Test groups: TS in FCA - Control group: FCA only - Site: R flank - Frequency of applications: every 2nd day - Duration: 0-8 d - Concentrations: same throughout B. CHALLENGE EXPOSURE - No. of exposures: 2 - Day(s) of challenge: 22 & 35	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.DetailsOnStudyDesign

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	<ul style="list-style-type: none"> - Exposure period: - - Test groups: TS - Control group: TS - Site: L flank - Concentrations: 4 different - Evaluation (hr after challenge): 24, 48, 72 		
Challenge controls	Discuss the use of a challenge (i.e. naïve) control group: number and sex of animals, dose for challenge application.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.ChallengeControls
Positive control substance(s)	Indicate if positive control substance(s) was/were used. If yes, describe the positive control(s) in supplementary field as appropriate. If no, describe any periodic or historic positive control(s).	Close list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.PositiveControlSubstances
Study design: in vivo (LLNA)		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale must be provided.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Vehicle
Concentration	Describe dose selection, i.e. at least 3 consecutive concentrations (100%, 50%, 25%, 10%, 5%, 2.5%, 1%, 0.5% etc.) of the test substance. Adequate scientific rationale should accompany the selection of the concentration series used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Concentration
No. of animals per dose	Provide number of animals per dose or range if different numbers were used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.NoOfAnimalsPerDose
Details on study design	For LLNA, LLNA:DA or LLNA:BrdU-ELISA, describe details on materials and methods as indicated in the freetext template. Enter any details that could be	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.Study

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	<p>relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <ul style="list-style-type: none"> - Details on radio isotope: to be included in field 'Details on test material' - RANGE FINDING TESTS: Briefly describe compound solubility, irritation and lymph node proliferation response if significant. - PRE-SCREEN TESTS: Briefly describe compound solubility, irritation, systemic toxicity (changes in: nervous system function, behaviour, respiratory patterns, food and water consumption), ear thickness measurements, erythema scores (0-3 on any day of measurement). <p>MAIN STUDY</p> <ul style="list-style-type: none"> - ANIMAL ASSIGNMENT AND TREATMENT: Indicate name of test method used. Comment on criteria used to consider a positive response. - TREATMENT PREPARATION AND ADMINISTRATION: Describe dose preparation and administration. (e.g. for LLNA:BrDU-ELISA 25 µl of compound x was applied to the entire dorsal surface of each ear of each mouse. The application was repeated on days 2 and 3). On day 5 an injection of 0.5 ml (5mg/mouse) of BrdU (10 mg/ml) solution was made inter-peritoneally for each experimental mouse. Twenty-four hours later, the draining auricular lymph node of each ear was excised into PBS (indicate individual animal approach or pooled animal approach). A single cell suspension of lymph node cells was prepared from each mouse (describe method of cell suspension). 		DesignInVivoLLNA.DetailsOnStudyDesign
Positive control substance(s)	<p>Indicate the positive control substance(s) used and give additional remarks in supplementary field as appropriate, e.g. the concentration used. Multiple selection is possible. If not listed, select 'other' and specify.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.PositiveControlSubstances
Statistics	<p>Provide the statistical procedures employed (e.g., linear regression analysis or William's test to assess dose-response trends; Dunnett's test to make pairwise comparisons).</p>	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Statistics
Any other information	<p>Any other information on materials and methods included - (H2) – common block</p>	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.

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on materials and methods incl. tables			AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion
Positive control results	Discuss the positive control results and demonstrate that the laboratory has the capability to identify positive dermal sensitizers.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.PositiveControlResults
In vitro / in chemico		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico
Results	Indicate the test results. Copy this block of fields as appropriate. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.KeyResult
Group		Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.Group

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Run / experiment	Indicate the run / experiment the measurement relates to.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.RunExperiment
Parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. Please include EC150 and EC200 values, if those can be calculated.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.Parameter
Value	Indicate also the unit of measurement e.g. μM , mM, $\mu\text{g/ml}$, mg/ml etc.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.Value
At concentration		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.AtConcentration
Cell viability		Text area	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.CellViability
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. without test substance, with/without solvent) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) is valid, i.e. substance(s) with known lack of irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) is valid, i.e. substance(s) with known irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.

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		remarks	InVitroInChemico.Results.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.RemarksOnResults
Results			
Outcome of the prediction model	For DPRA, the mean peptide % depletion values have been specified for each reactivity group in the test guideline for each prediction model.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.PredictionModelOutcome
Other effects / acceptance of results	Use freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system) - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative control, positive control, and variability between replicate measurements) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.OtherEffectsAcceptanceOfResults
In vivo (non-LLNA)		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest
Results	Record the results of in vivo non-LLNA tests at the different readings for each test or control group used.		ENDPOINT_STUDY_RECORD.SkinSensitisation

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	Copy this block of fields as appropriate. Present the scores from the challenge responses in a table. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.		.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.KeyResult
Reading	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.Reading
Hours after challenge	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.HoursAfterChallenge
Group	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.Group
Dose level	If more than one concentration was tested at challenge, specify the concentration(s) the reading refers to, e.g. '0.15 g of a 10% aqueous solution'. Several dose levels can be given if the results reported in this block of fields is the same for all challenge groups, e.g. '0.15 or 0.3 g of a 10% aqueous solution'.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.DoseLevel
No. with + reactions	Enter numeric value.	Integer	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.NoWithReactions

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Total no. in group	Enter numeric value.	Integer	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.TotalNoInGroup
Clinical observations	Briefly describe relevant clinical observations.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.ClinicalObservations
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.RemarksOnResults
Results			
In vivo (LLNA)		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA
Results	Indicate the cell proliferation results for the test substance, i.e. either ATP (measured adenosine triphosphate content of lymphocytes) or BrdU (measured 5-bromo-2-deoxyuridine content in DNA of lymphocytes) or DPM (incorporated radioactivity as disintegrations per minute) or other. Copy this block of fields as appropriate. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Cellular proliferation data / Observations" and/or upload a table in the field "Any other information on		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results

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	<p>results incl. tables".</p> <p>Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.KeyResult
Parameter	<p>Select type of parameter from picklist, if applicable, i.e. either SI (stimulation index) or EC3 (estimated concentration of a test substance needed to produce a stimulation index of three) or ECt (estimated concentration of a test substance needed to produce a stimulation index that is indicative of a positive response) or other (specify). Further details can be given in the supplementary remarks field.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Parameter
Value	<p>Provide the numeric value or a range of values if reported so.</p> <p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range (Decimal)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Value
Variability	<p>Indicate the standard deviation or other appropriate measure of variability that takes into account the inter-animal variability in both the test substance and control groups when using the individual animal approach.</p>	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Variability
Test group / Remarks	<p>Indicate the concentration of the test material, the run / experiment number the calculated value relates to and any other relevant information. Examples: Exp. 1 (0%); Exp. 1 (0.5%); Exp. 1 (1%), etc. or Mean of three runs (0%), etc.</p>	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.TestGroupRemarks
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.RemarksOnResults
Results			

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<p>Cellular proliferation data / Observations</p>	<p>For robust study summaries or as requested by the regulatory programme, tabulate the raw data (unless these data are given in above block of fields 'Stimulation index / EC value') and indicate any relevant observations. Use freetext template and delete/add elements as appropriate. Alternatively or in addition refer to appropriate table(s), which were uploaded in the rich text field 'Any other information on results incl. tables'. Use predefined table if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them (e.g. '... see Table 1'). Provide the results of cellular proliferation measurements (DPM values for conventional LLNA or ATP content values for LLNA: DA or BrdU content values for LLNA: BrdU-ELISA). Comment on dose-response trends and comparisons with the vehicle control group. Give statistical comparisons of group mean measurements compared to control. Indicate whether results are from the individual animals or pooled. Indicate whether the overall result is positive or negative. Note: Specific tables may be required.</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.CellularProliferationDataObservations</p>
<p>Any other information on results incl. tables</p>	<p>Any other information on results incl. tables Block</p>	<p>Header 2</p>	<p>ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables</p>
<p>Overall remarks, attachments</p>	<p>Overall remarks, attachments – common block</p>	<p>Header 1</p>	<p>ENDPOINT_STUDY_RECORD.SkinSensitisation.OverallRemarksAttachments</p>
<p>Applicant's summary and conclusion</p>	<p>Applicants summary and conclusion – common block</p>	<p>Header 1</p>	<p>ENDPOINT_STUDY_RECORD.SkinSensitisation.ApplicantSummaryAndConclusion</p>

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7.1.6 Supplementary studies on the plant protection product - Endpoint study record

Purpose:

Provide information:

- For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant.
- For volatile active substances (vapour pressure >10–2 Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes - v.7.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Species: NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.TestAnimals

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	reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.		
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Briefly describe details of exposure.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Doses	Include the doses including unit administered to the test animals, '5, 50, 500 and 2000 mg/kg bw'. As appropriate include notes in parentheses, e.g. '(male)'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether concurrent control group was used.	Open list with	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.Material

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		remarks	sAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the LD50 or other.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion
Effect levels	Provide the LD50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. If no LD50 or other endpoint available from picklist is reported, but only a dose level, specify this dose using 'other' and indicate the effects observed in subfield 'Remarks on result'.		ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.Sex

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Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 mg/kg bw or LD50 <10 mg/kg bw. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			

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Mortality	Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ApplicantSummaryAndConclusion
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7.2 Data on exposure – Endpoint summary

<p>Purpose Chemical and Microorganism: To report an overview of the non-dietary exposure estimates for operator, worker, bystander and resident as a percentage of the AOEL and AAOEL, if appropriate, according to the representative uses evaluated. The document is reflecting the list of end points for non-dietary exposure (SANCO/12592/2012-rev. 2, 22 March 2019).</p>
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FLEXIBLE_SUMMARY.NonDietaryExpo – v.1.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.NonDietaryExpo.AdministrativeDataSummary
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_SUMMARY.NonDietaryExpo.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)	Provide here the link to critical and non-critical GAP descriptions.	Header 1	FLEXIBLE_SUMMARY.NonDietaryExpo.LinkToRelevantStudyRecord
Study name / type	FLEXIBLE_RECORD.GAP	Endpoint reference list	FLEXIBLE_SUMMARY.NonDietaryExpo.LinkToRelevantStudyRecord.Link
Results		Read-only	FLEXIBLE_SUMMARY.NonDietaryExpo.LinkToRelevantStudyRecord.Results
Description of key information	Enter a short description of the most relevant summary data.	Header 1	FLEXIBLE_SUMMARY.NonDietaryExpo.KeyInformation

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	EFSA Guidance on Non-Dietary exposure, 2014, DOI:10.2903/j.efsa.2014.3874 can be consulted when preparing this summary.		
		Rich text area	FLEXIBLE_SUMMARY.NonDietaryExpo.KeyInformation.KeyInformation
Description of use	n.a.: Header	Header 1	FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse
Uses	Block of fields (repeatable)		FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse.Uses
Use description	Include a brief description of the use. For example: "Use: potatoes, tractor mounted equipment, application rate 2.5 kg a.s./ha	Rich text area	FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse.Uses.UseDescription
Exposure scenarios	n.a.: Header	Header 2	FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse.Uses.ExposureScenarios
Operator exposure		Header 3	FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse.Uses.ExposureScenarios.OperatorExposure
	Describe the model, and the resulting exposure estimates (% of AOEL/%AAOEL, with appropriate personal protective equipment if necessary)	Rich text area	FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse.Uses.ExposureScenarios.OperatorExposure.OperatorExposure
Worker exposure		Header 3	FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse.Uses.ExposureScenarios.WorkerExposure
	Describe the model, and the resulting exposure estimates (% AOEL/AAOEL, with appropriate personal protective equipment if necessary)	Rich text area	FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse.Uses.ExposureScenarios.WorkerExposure.WorkerExposure
Bystander / resident exposure		Header 3	FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse.Uses.ExposureScenarios.BystanderResidentExposure
	Describe the model, and the resulting exposure estimates (% of AOEL/%AAOEL, with appropriate personal protective equipment if necessary)	Rich text area	FLEXIBLE_SUMMARY.NonDietaryExpo.DescriptionOfUse.Uses.ExposureScenarios.BystanderResidentExposure.BystanderResidentExposure
Uses			

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Additional information	Discussion (Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.NonDietaryExpo.Discussion
	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Rich text area	FLEXIBLE_SUMMARY.NonDietaryExpo.Discussion.Discussion
Attached background material	<p>Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).</p> <p>Copy this block of fields for attaching more than one file.</p>		FLEXIBLE_SUMMARY.NonDietaryExpo.Discussion.AttachedBackgroundMaterial
Attached document	<p>Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document.</p> <p>The excel calculator from the EFSA Guidance (2014) should be provided.</p>	Single file attachment	FLEXIBLE_SUMMARY.NonDietaryExpo.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	<p>As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory</p>	Text	FLEXIBLE_SUMMARY.NonDietaryExpo.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			

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Attached (sanitised) documents for publication	If required, an electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. These attachments should be sanitised if needed.	Attachments list	FLEXIBLE_SUMMARY.NonDietaryExpo.Discussion.AttachedSanitisedDocsForPublication
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Links to support materials

SANCO/12592/2012-rev. 2, 22 March 2019. [Templates To Be Used For Assessment Reports and Proposals for Classification](#) - [Word Version](#) - March 2019

EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, 2014. Available online:

<https://www.efsa.europa.eu/en/efsajournal/pub/3874>

Richardson, Jane, Grosskopf, Claudia, Hamey, Paul Y, Machera, Kyriaki, Martin, Sabine, Jacobi, Lena Elisabeth, & Tiramani, Manuela. (2016, October 17). Exposure of operators, workers, residents and bystanders in risk assessment for plant protection products calculator (Version 30MAR2015). Zenodo.

<http://doi.org/10.5281/zenodo.161298>

7.2 Data on exposure– Endpoint study record

Purpose:

Where available, reports from studies with humans, such as tests on toxicokinetics and metabolism, or tests on skin irritation or skin sensitisation, shall be submitted. In general, the reference values shall be based on animal studies, but if appropriate scientifically valid and ethically generated human data are available and show that humans are more sensitive and lead to lower regulatory limit values, these data shall take precedence over animal data.

This document can also be used to report Dislodgeable Foliar Residues studies cited in operator exposure assessments.

ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther - v.7.3 (Final) [September 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialAndMethods

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			vationsOther.MaterialsAnd Methods
Type of study / information	Briefly indicate the type of information (which does not fit into any of the specific chapter.)	Multi-line text	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAnd Methods.TypeOfStudyInformation
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.	Multi select open list	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAnd Methods.EndpointAddressed
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAnd Methods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAnd Methods.Method
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAnd Methods.Method.EthicalApproval
Details on study design	Describe the study design including any relevant information from a study report, publication or other source. Include or attach tables or excerpts from study report as appropriate.	Text area	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAnd Methods.Method.DetailsOnStudyDesign
Exposure assessment	Indicate whether the exposure was measured or estimated. For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAnd Methods.Method.ExposureAssessment
Details on exposure	Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Explanations: - TYPE OF EXPOSURE: Characterise type of exposure including information on manufacturing /	Text template	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAnd Methods.Method.DetailsOnExposure

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	<p>processing / use as applicable. If available, describe special exposure situations / workplaces.</p> <ul style="list-style-type: none"> - TYPE OF EXPOSURE MEASUREMENT: Indicate relevant predefined type(s); delete those being not applicable. - EXPOSURE LEVELS: Give exposure level(s) reported (with units) or insert/attach table, for several exposure conditions and levels. - EXPOSURE PERIOD: Describe when subjects were exposed and duration of exposure, i.e., hours, hours per day, days, days per week, weeks, months, years, person years, other. - POSTEXPOSURE PERIOD: State period of time elapsed between last exposure/first examination or time study was conducted. - DESCRIPTION / DELINEATION OF EXPOSURE GROUPS / CATEGORIES: If several exposure groups (e.g. different concentrations or durations) are analysed, identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc. 		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion
Results	Provide exposure data as available and describe any relevant outcome of the study. If appropriate present the data in tabular form and/or attach excerpt(s) from the study report.	Text area	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion.Results
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ApplicantSummaryAndConclusion
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7.3 Dermal absorption – Endpoint summary

<p>Purpose: Chemical: Conclude on the dermal absorption values of the active substances and if needed, of toxicologically relevant compounds in the plant protection product. The document is reflecting the list of end points for dermal absorption (SANCO/12592/2012-rev. 2, 22 March 2019). Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)</p>

ENDPOINT_SUMMARY.DermalAbsorption v1.1 (Final)			
Name	Instructions	Data type	Field path
Administrative data	The general rules on confidentiality requests apply in setting the flags (Administrative data summary – common block). See section on Confidentiality of dossiers	Header 1	ENDPOINT_SUMMARY.DermalAbsorption.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.DermalAbsorption.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)	Provide here the link to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.	Header 1	ENDPOINT_SUMMARY.DermalAbsorption.LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	ENDPOINT_SUMMARY.DermalAbsorption.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.DermalAbsorption.LinkToRelevantStudyRecord.Results
Description of key information	Enter a short description of the most relevant endpoint data. The short description could include for example:	Header 1	ENDPOINT_SUMMARY.DermalAbsorption.KeyInformation

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	Representative formulation (indicate name, type e.g. EC and concentration of active substance)		
		Rich text area	ENDPOINT_SUMMARY.Dermal Absorption.KeyInformation.KeyInformation
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Dermal Absorption.KeyValueCsa
Endpoint	Select the relevant endpoint addressed by this study summary.	Closed list with remarks	ENDPOINT_SUMMARY.Dermal Absorption.KeyValueCsa.Endpoint
Type of information	Select the appropriate type of information. The option 'not specified' should be selected if the submitter lacks the knowledge of the type of information. The option 'other:' can be used if another than a pre-defined item applies.	Open list with remarks	ENDPOINT_SUMMARY.Dermal Absorption.KeyValueCsa.TypeOfInformation
Justification	When pro rata or read across is applied.	Multi-line text	ENDPOINT_SUMMARY.Dermal Absorption.KeyValueCsa.Justification
Species	Select as appropriate. For in vitro tests, indicate the species used as source of the skin samples. If not available from picklist, select 'other:' and specify.	Multi select open list	ENDPOINT_SUMMARY.Dermal Absorption.KeyValueCsa.Species
Results			ENDPOINT_SUMMARY.Dermal Absorption.KeyValueCsa.Results
Concentration in g/L	Indicate the concentration for the tested concentrated product, the tested dilutions and in use dilution'. Dermal absorption for the in-use dilution could be calculated	Decimal	ENDPOINT_SUMMARY.Dermal Absorption.KeyValueCsa.Results.Concentration

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	from the tested dilution and corrected (specific cases, pro-rata).		
Parameter	Select the relevant absorption parameter, i.e. percentage.	Open list with remarks	ENDPOINT_SUMMARY.Dermal Absorption.KeyValueCsa.Results.Parameter
Absorption		Range with open list (Decimal)	ENDPOINT_SUMMARY.Dermal Absorption.KeyValueCsa.Results.Absorption
Results			
Additional information	<p>Discussion (Header 1) – common block</p> <p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Header 1	ENDPOINT_SUMMARY.Dermal Absorption.Discussion
	Provide any additional information related to the endpoint.	Rich text area	ENDPOINT_SUMMARY.Dermal Absorption.Discussion.Discussion
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image		ENDPOINT_SUMMARY.Dermal Absorption.Discussion.AttachedBackgroundMaterial

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	of a structural formula). Copy this block of fields for attaching more than one file.		
Attached document	The original file only needs to be attached here if it differs from the non-confidential file uploaded under “Attached (sanitised) documents for publication”. If a file is uploaded under this field a confidentiality claim must be submitted for each part of the file considered confidential.	Single file attachment	ENDPOINT_SUMMARY.Dermal Absorption.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	ENDPOINT_SUMMARY.Dermal Absorption.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to	Attachments list	ENDPOINT_SUMMARY.Dermal Absorption.Discussion.AttachedSanitisedDocsForPublication

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	confidentiality requests that were rejected in part or in full must be uploaded here. Please provide BfR template for <i>in vitro</i> calculations.		
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Links to support material:

Guidance on Dermal Absorption [doi:10.2903/j.efsa.2017.4873](https://doi.org/10.2903/j.efsa.2017.4873)

Dermal absorption: refined BfR template for *in vitro* calculations.

Available online: <https://www.efsa.europa.eu/en/press/news/171207-0>

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7.3 Dermal absorption – Endpoint study record

Purpose:

The dermal absorption of plant protection products to be authorised can be measured in vitro and/or in vivo.

The study shall be conducted when dermal exposure is a significant exposure route, and no acceptable risk is estimated using default absorption value.

The dermal absorption through skin shall be provided for the active substances and toxicologically relevant metabolites.

Studies shall be performed on representative plant protection products at both in use dilution (when applicable) as well as the concentrated form.

The in vitro method provides information on absorption of a test substance applied to excise skin to a receptor fluid.

For the in vivo percutaneous absorption the test substance is applied to the clipped skin of animals at one or more appropriate dose levels in the form of a representative in-use preparations.

At the end of the exposure time all samples are assayed by appropriate means and the degree of absorption is estimated.

Beside the measured amount of active substance in the receptor fluid / degree of percutaneous absorption an estimation of the accuracy and measurement uncertainty if available is to report. Any deviation from the guideline method used or any other special consideration should be reported.

ENDPOINT_STUDY_RECORD.DermalAbsorption v.7.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.DermalAbsorption.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.DermalAbsorption.DataSource
Materials and methods	Material and methods – common block Applicable Test guideline: OECD Test Guideline 428: Skin absorption: in vitro method	Header 1	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods

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	<p>OECD Test Guideline 427: Skin absorption: in vivo method</p> <p>Method B.44 Skin absorption: in vivo method. (Annex of Regulation (EC) No 440/2008).</p> <p>Method B.45 Skin absorption: in vitro method. (Annex of Regulation (EC) No 440/2008).</p> <p>OECD Guidance notes on dermal absorption, Series on Testing and Assessment No. 156, ENV/JM/MONO (2011)36. WHO, 2006. Environmental Health Criteria, 235. Dermal Absorption. (12) EFSA Scientific Opinion of PPR Panel - Guidance on Dermal Absorption EFSA Journal 2012; 10 (4):2665.</p>		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be	Open list with remarks	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.TestMaterials.Radiolabelling

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	described in field 'Details on test material'. In the supplementary remarks field, any further explanations can be provided, e.g. for indicating that both labelled and unlabelled substances were used.		
Test animals	Test animals (OHT: Repeated dose toxicity)	Header 2	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.TestAnimals
Species	Select as appropriate. For in vitro tests, indicate the species used as source of the skin samples. If not available from picklist, select 'other' and specify. Note: If human skin was used in an in vitro test, comment on ethical approval in field 'Details on in vitro test system'.	Open list	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.TestAnimals.Species
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AdministrationExposure
Type of coverage	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AdministrationExposure.TypeOfCoverage
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the	Open list with remarks	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AdministrationExposure.Vehicle

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	<p>supplementary remarks field.</p> <p>Note that some of the vehicles provided in this list are used for specific routes of administration only.</p>		
Duration of exposure	<p>Indicate the time interval between application and removal of test preparation by skin washing, e.g. '6 hours'. Describe when termination occurred. Explain if some groups were terminated at wash and some were washed, then terminated later.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AdministrationExposure.DurationOfExposure
Doses	<p>As appropriate enter text or use freetext template and delete/add elements. Indicate the nominal and, if available, the actual doses including unit applied to the test animals (e.g. '0.0X, 0.X, and X.0 µg ai/X cm² skin over all duration periods'). Also state the dose volume (e.g. in ml/cm²) and provide the rationale for dose selection (explain, e.g., anticipated dermal deposition in the field). Modify any unit in the freetext template as appropriate.</p> <p>For i.v. dosing, specify whether the same animal is used for intravenous and dermal dosing.</p> <p>In case of a robust</p>	Text template	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AdministrationExposure.Doses

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	<p>study summary or as requested by the regulatory programme, also provide a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>		
No. of animals per group	<p>Indicate number of animals per group of one sex, i.e. each test preparation and each scheduled termination time. If numbers differ, specify, e.g. '4 in all groups but one; 3 in 2 mg/cm² group scheduled for termination at 48 hours'.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerGroup
Control animals	<p>Indicate whether control groups were used and specify or comment in supplementary remarks field as appropriate.</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	<p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective</p>	Text template	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

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	<p>regulatory programme. Explanations: DOSE PREPARATION: e.g., combining appropriate amounts of the radioactive and non-radioactive formulation, and water and thoroughly mixing. APPLICATION OF DOSE: provide details on how the dose was applied (e.g., X µL was applied and spread evenly across the surface of the skin site using (e.g., a glass rod). The glass rod used to apply the dose was (e.g. rinsed with X ml of methanol, wiped with a gauze pad and the rinse and wipe collected for analysis).). TEST SITE: - Preparation of test site: e.g. shaved (or discuss); shaved area washed with XXXX. Abrasion? - Area of exposure: expressed in cm² - % coverage / - Type of cover / wrap if used: provide data on the percentage and type of coverage (e.g., The dosing enclosure was covered by (e.g., a nonocclusive filter paper cover attached using rubber cement)). SITE PROTECTION / USE OF RESTRAINERS FOR PREVENTING INGESTION: indicate if</p>		
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	<p>restrainers (spacers) were used and what type (e.g. Elizabethan collar placed on each animal's neck). REMOVAL OF TEST SUBSTANCE: Describe timing, removal of apparatus, washing procedures, other approaches used (e.g., tape stripping), etc. SAMPLE COLLECTION: Describe sample collection during the exposure period and until termination of study (e.g. urine, faeces, blood, expired air), procedures for termination, analysis of organs (e.g., Skin from application site; blood; residual urine; residual carcass; cover, cage wahings and other potentially contaminated equipment).</p>		
<p>Details on in vitro test system (if applicable)</p>	<p>In the case of in vitro testing give details on the skin preparation. Include source of skin (State what type of skin was used, i.e. viable or non-viable skin, epidermal membranes or split / full thickness skin). Give details on how skin was prepared and any treatment(s) (heat separation, chemical or enzymatic separation). Include data on any check for membrane integrity.</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AdministrationExposure.DetailsOnInVitroTestSystemIfApplicable</p>

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	Briefly describe the principles of the assay. Note: Enter information on duration, application, sampling and analysis in the respective fields. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Any other information on materials and methods incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.DermalAbsorption.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion
Signs and symptoms of toxicity	Indicate whether signs and symptoms of toxicity were observed or not. If yes, describe the effects at the different doses in the supplementary remarks field. In addition or as an alternative option, include a table and refer to the respective table no.	Closed list with remarks	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.SignsSymptomsToxicity
Dermal irritation	Indicate whether any dermal irritation were observed or not. If yes, describe the effects and at what doses in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.DermalIrritation

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<p>Absorption in different matrices</p>	<p>Include the dose recovery in the various matrices, i.e. amount of compound in each sample (% of dose applied). The dose recovery should include skin wash, cover and enclosure (if applicable), carbon filter (if applicable), tape stripping (if applicable), urine, cage wash and wipe , faeces, expired air, carcass and skin application site. Use freetext template delete/add elements as appropriate. For very comprehensive data refer to summary tables for each dose level (e.g. predefined table). Include table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.AbsorptionMatrices</p>
<p>Total recovery</p>	<p>Include the total recovery and information on its validity. Use freetext template delete/add elements as appropriate.</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.TotalRecovery</p>

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	<ul style="list-style-type: none"> - Total recovery: e.g., Total amounts of radioactivity in samples were reported as a percentage of the total dose (or discuss). - Limit of detection (LOD): e.g., Limits of detection were established as follows: range µg/g sample for the low dose group, range µg/g sample for the medium dose group and range µg/g sample for the high dose group. [or note if this data not reported] - Quantification of values below LOD or LOQ: describe how values below LOD or LOQ were quantified (i.e. values < LOD = 1/2 LOD or 0). 		
Percutaneous absorption	Include the most appropriate mean dermal absorption value. Copy this block of fields for different dose groups as appropriate.		ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.Absorption
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.Absorption.KeyResult
Time point	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.DermalAbsorption

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			n.ResultsAndDiscussion .Absorption.TimePoint
Dose	Indicate the group for which the absorption value is provided, e.g. '2 g/cm ² skin'. As appropriate several groups may be included, for example if absorption was less than a certain percentage in all groups.	Text	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.Absorption.Dose
Parameter	Select the relevant absorption parameter, i.e. rate, amount or percentage.	Open list with remarks	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.Absorption.Parameter
Absorption	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.Absorption.Absorption
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.Absorption.RemarksOnResults

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	additional information by selecting 'other:'.		
Percutaneous absorption			
Conversion factor human vs. animal skin	If a conversion factor was derived to account for the difference in permeability between human and animal skin, provide this factor including details on the calculation basis, e.g. based on differences in absorption rates or in flux as applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.ConversionFactor
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.DermalAbsorption.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.DermalAbsorption.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DermalAbsorption.ApplicantSummaryAndConclusion

8 Residues in or on treated products, food and feed

9 Fate and behavior in the environment – Endpoint summary

Purpose:

Provide summary information of the most relevant study(-ies) from which the key value for assessment is extrapolated. Provide only the most relevant details related to:

Mobility

Microorganisms: Persistence and multiplication (competitiveness) in soil, water and air

Chemicals: Fate and behaviour in soil, water and air

This document can be used to summarise information from a range of different studies to conclude on specific aspects of fate and behaviour or persistence and multiplication in the environment

This document can be used to provide an overarching discussion of the data and how it was handled for the purposes of establishing endpoints.

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ENDPOINT_SUMMARY.EnvironmentalFateAndPathways v.5.0 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block Description of key information: Enter a short description of the most relevant endpoint data. The short description could include for example: -the test guideline used, -the test organism, -the exposure duration, -the contextual information of the origin of the value, -qualitative characterisation of some properties	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.Discussion

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9.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies) - Endpoint study record

Purpose:

These experiments are performed to determine the route and the rate of transformation of the test substance in soil, and to determine the nature and rates of formation of transformation products.

Principle of the study:

- The microbial biomass of soils used for laboratory degradation studies shall be determined immediately before the commencement and at the end of the study.
- The soils used for degradation studies shall be representative of the range of agricultural soils typical of the various regions of the Union where use exists or is anticipated.
- The soils shall fulfil the following conditions: they shall cover a range of organic carbon content, particle size distribution and where on the basis of other information, degradation is expected to be pH dependent, they shall cover approximately the following pH (preferably measured in CaCl₂) ranges: 5 to 6, 6 to 7 and 7 to 8.
- Soils used shall, wherever possible, be freshly sampled. If use of stored soils is unavoidable, storage shall be carried out for a limited time (at the most three months) under defined and reported conditions, which are adequate to maintain soil microbial viability. Soils stored for longer periods of time may only be used for adsorption/desorption studies.
- A soil having extreme characteristics with respect to parameters such as particle size distribution, organic carbon content and pH shall not be used.

ENDPOINT_STUDY_RECORD.BiodegradationInSoil – v6.4 (Final) [October 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Microbial Pesticide Test Guidelines OPPTS 885.5200 Expression in a Terrestrial Environment	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods
Test type	Indicate whether the study was a field trial or laboratory study.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestType

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Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Close list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign
Oxygen conditions	Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.OxygenConditions
Soil classification	Select as cited in the study report. If not available from picklist, select 'other:' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilClassification
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field 'Report date'.	Integer	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.Year
Soil properties	Repeat this block of fields for each different soil used as indicated by the Soil No. Enter soil type as cited in the study report and the respective soil properties.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties
Soil no.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.SoilNo
Soil type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDes

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			ign.SoilProperties.Soi lType
% Clay	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Cla y
% Silt	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Silt
% Sand	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Sa nd
% Org. C	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Or gC
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Ph
CEC	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.CE C
Bulk density (g/cm³)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Bul kDensityGcm
% Moisture content	Moisture content of the soil (at pF 2 or at Maximum Water Holding Capacity). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes

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	is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		ign.SoilProperties.MoistureContent
Soil properties			
Details on soil characteristics	For each soil type, specify soil collection and storage and properties of the soil as far as not indicated in the defined fields. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSoilCharacteristics
Duration of test (contact time)	Specify duration of test in terms of contact time. Repeat block for each soil type. If different test runs have different durations, enter lower and upper value in respective subfields.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime.SoilNo
Duration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime.Duration
Duration of test (contact time)			
Initial test substance concentration	Specify the initial test concentration applied. If different concentrations were used in different test runs, copy this block of fields accordingly. If a range of concentrations is reported, include the lower and upper values in the numeric range field. If appropriate copy this block of fields for indicating different parameters the initial concentration is based on (e.g. COD and test substance).		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDes

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			ign.InitialTestSubstanceConcentration.SoilNo
Initial conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.InitialConc
Based on	From drop-down list, select the parameter on which the initial concentration is based.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.BasedOn
Initial test substance concentration			
Parameter followed for biodegradation estimation	Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as appropriate. In supplementary remarks field, give relevant details on the method. For radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ParameterFollowed
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products and/or non-extractable residues.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods
Experimental conditions	For each soil type, indicate the environmental conditions during the test if available or assumed in the model, if estimated.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.Biodegrada

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			tionInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.SoilNo
Temp.	Specify test temperature including mean and range values during test if available or temperature assumed in the model, if estimated. Use °C; convert other units and indicate original data in parentheses if applicable.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.Temp
Humidity	Indicate soil humidity in % moisture content or g water/100g soil dry weight.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.Humidity
Microbial biomass	Indicate initial and final microbial biomass / microbial population of control and treated soil, if provided. Specify unit, e.g., mg biomass/100 g soil dry weight or µg C/g soil.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.MicrobialBiomass
Experimental conditions			
Details on experimental conditions	Include Soil No. in parentheses if conditions were not identical for all soil types tested. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnExperimentalConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion

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Material (mass) balance	If applicable, indicate mean total recovery of test material as percentage of applied amount +/- standard deviation. Copy this block of fields for each soil type as appropriate.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.SoilNo
Sampling date	Enter the date the sample was taken	Date	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.SamplingDate
% Total extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.TotalExtractable
% Non extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.NonExtractable
% CO2	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.CO2
% Other volatiles	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.OtherVolatiles
% Recovery	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.Recovery
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.Biodegrada

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			tionInSoil.ResultsAnd Discussion.MaterialMassBalance.StDev
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.MaterialMassBalance.RemarksOnResults
Material (mass) balance			
% Degradation	For each soil type, indicate percentage of degradation of test substance including standard deviation at the end of the study period. Also indicate on what parameter the degradation rate is based on (e.g. 'radiochemical measurement'). If required, copy block of fields to include values based on different parameters.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation
Parent/product	Indicate if the result reported is for the active substance/parent or the product/metabolite. The identify of the substance can be selected below	Close list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.ParentProduct
Name or code for product	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.NameOrCodeForProduct
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.SoilNo
Sampling date	Enter date when the sample was taken	Date	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.SamplingDate

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% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.Degr
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.StDev
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.Parameter
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SamplingTime
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Half-life / dissipation time of parent compound	For each soil type, include value (or range if reported so) of half-life and indicate the type of half-life (For first order kinetics DT50 = half-life).		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOf

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			ParentCompound.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.SoilNo
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.HalfLife
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.StDev
Type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.Type
Temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.Temp
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.RemarksOnResults
Half-life / dissipation time of parent			

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compound			
Transformation products	<p>Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.</p> <p>Not relevant for microorganisms</p>	Close d list with rema rks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	<p>Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance.</p> <p>Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.</p>		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation
No.	<p>For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.</p>	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	<p>Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.</p>	Entity refere nce field	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on transformation products	<p>Indicate any relevant supplementary information on transformation products. Use freetext template and delete/add items as appropriate. If useful attach a figure in the corresponding field.</p>	Text templ ate	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.TransfProductsDetails
Evaporation of parent compound	<p>Indicate whether evaporation of the parent compound occurred or not. Include any explanations in field 'Details on results' as appropriate.</p> <p>'Yes' should be selected when CO₂ has been detected in volatile traps.</p>	Close d list with rema rks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.EvaporationOfParentCompound

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Volatile metabolites	Indicate whether volatile metabolites were found or not. Include any explanations in field 'Details on results' as appropriate.	Close d list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.VolatileMetabolites
Residues	Indicate whether residues were found or not. Include any explanations in field 'Details on results' as appropriate.	Close d list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Residues
Details on results	<p>Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>In field 'Attached background material', attach graph(s) with the full degradation or elimination curves.</p> <p>TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.</p> <p>MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table.</p> <p>STERILE TREATMENTS: If used, report the transformation of the parent, and compare the results with those of the non-sterile treatments:</p> <p>SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.</p>	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.DetailsOnResults
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.ResultsWithReferenceSubstance
Any other information on	<p>Any other information on results incl. tables Block</p> <p>For Microorganisms the tables in the results and discussion section do not need to reported unless suitable data is available. However Tabulation/graphs of</p>	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.AnyOther

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results incl. tables	population dynamics and Discussion of test results should be provided in this field.		InformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.OverallRemarksAttachments
Kinetic evaluation	The filled "Template 7.1 - template for presentation of kinetic fitting" (https://doi.org/10.5281/zenodo.4557253) shall be uploaded here to report the the visual and statistical kinetic evaluation.	Attachments list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.OverallRemarksAttachments.KineticEvaluation
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ApplicantSummaryAndConclusion

9.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies)-Endpoint Summary

Purpose:

Summarise the results of the laboratory studies on the rate of degradation in soil reporting all relevant information on the properties of the soils, the rates of degradation for persistence and modelling for active substance and its metabolites, and the correspondent kinetic models used.

ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP - v.1.3 (Final) [October 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Report Information to support the persistence /rate of degradation in soil. Make reference to the studies used to conclude on the rate of degradation in soil.	Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.AdministrativeDataSummary

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	Multiple endpoint summaries can be created where different DegT50 values are defined at different pH values. The pH should be specified in the 'Description of key information field		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa
Persistence / rate of degradation in soil			ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.Substance
Test conditions	Provide information on the test conditions, aerobic or anaerobic	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.TestConditions
Soil type	Enter the type of soil used in the laboratory test system.	Text	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.SoilType
pH	Enter the pH value of the soil in the laboratory test system.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the soil pH was measured.	Multi-line text	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.MeasuredIn

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Soil moisture (%)	Enter the soil moisture at which the incubation was carried out (e.g.: maximum water holding capacity (%) or pF2 (%) or pF2.5 (%) values).	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .SoilMoisture
Half-life in soil (DT50)	Enter the DT50 value for persistence.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .HalfLifeSoil
DT90 in soil	Enter the DT90 value for persistence.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .DtNinetySoil
at the temperature of	Enter the temperature of the soil in the laboratory test system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .Temperature
Chi-square (χ^2)	Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for persistence.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_E

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	transformation products.		U_PPP.KeyValueCsa.PersistanceDegradationSoil.KineticFormationFracti on
Precursor	For metabolites, when relevant, select the precursor substance (e.g. the active substance or another metabolite).	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.PersistanceDegradationSoil.Precursor
Remarks	Provide any additional information needed to interpret the reported results	Text area	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.PersistanceDegradationSoil.Remarks
Persistence / rate of degradation in soil			
Modelling rate of degradation in soil			ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. Substance
Test conditions	Select the conditions of the study (aerobic/anaerobic).	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. TestConditions
Soil type	Enter the type of soil used in the laboratory test system.	Text	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. SoilType
pH	Enter the pH value of the soil in the laboratory test system.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. Ph

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measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the soil pH was measured.	Multi-line text	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.MeasuredIn
Soil moisture (%)	Enter the soil moisture at which the incubation was carried out (e.g.: maximum water holding capacity (%) or pF2 (%) or pF2.5 (%) values)	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.SoilMoisture
Normalised (DT50)	Enter the DT50 value for modelling at 20°C and pF2/10kPa, normalized using a Q10 of 2.58 and Walker equation coefficient of 0.7.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.NormalisedDtFifty
Chi-square (χ^2)	Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for modelling.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving modelling endpoint (normalised DT50); when biphasic kinetic model is used, it should be specified how the DT50 was derived (DT90 FOMC/3.32, DFOP slow phase, etc...).	Text	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.KineticParameters

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Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.KineticFormationFraction
Precursor	For metabolites, when relevant, select the precursor substance (e.g. the active substance or another metabolite).	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Precursor
Remarks		Text area	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Remarks
Modelling rate of degradation in soil			
Key value for safety assessment			ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.Substance
Half-life in soil (DT50)	Indicate the geometric mean (if not pH dependent) of the normalised DT50 values. If pH dependence is identified, values other than the geometric mean can be reported according to the pH dependency evaluation (please select "yes" in the "pH dependence" field).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.HalfLifeSoil

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Mean formation fraction	Indicate the arithmetic mean of the formation fraction (f.f. kf/kdp) values for the metabolite.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.FormationFraction
pH dependence	Select 'yes' or 'no' to indicate whether the result is pH dependent	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.PhDependence
Remarks		Text area	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.Remarks
Key value for safety assessment			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.Discussion

9.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies) - Endpoint Summary

Purpose: Summarise the results of studies on the aerobic and anaerobic route of degradation in soil and identify the metabolites requiring further consideration for risk assessment.			
ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and metabolites that should be considered for risk assessment	Header 1	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa
Route of degradation in soil	The route of degradation consists in:		ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP.

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	1) determining the amount mineralization; 2) determining the amount of non-extractable residues; 3) identifying metabolites above the regulatory trigger.		KeyValueCsa.Degradati onSoil
Parent / metabolite	Rows should be created for the active substance and each metabolite	Closed list	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.Substance
Test conditions	Indicate whether the results are for aerobic conditions, anaerobic conditions. A summary can be completed for each type of test condition.	Closed list	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.TestConditions
Sterile conditions	Indicate if the results were obtained under sterile conditions	Check box	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.SterileConditions
Mineralisation (%)	Indicate the mineralization percentage after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.Mineralisation
Non extractable residues (%)	Indicate the non-extractable residues percentage after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.MaximumOccurrence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.DayMaximumOccurrence

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Actual duration (days)	Report the duration of the study in days.	Integer	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.ActualDuration
Radio label	Provide information on the radio labelling used to obtain these results	Text	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.RadioLabel
Number soils	Report the number of soil analysed to obtain these results	Integer	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.NumberSoils
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.Remarks
Route of degradation in soil			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.Discussion

Links to support material:

DG SANCO Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides" (25.09.2012 – rev. 3)

ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment (revision 1)

9.1.2 Route and rate of degradation in soil (field studies) – Endpoint summary

Purpose:

Summarize the results of the field studies providing information on the transformation of the active substance, and if required its metabolites, under representative actual use conditions.

ENDPOINT_SUMMARY.FieldStudies – v.3.0 (Final) [July 2020]

Name	Instructions	Type	Field Path
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<p>Administrative data</p>	<p>Administrative data summary – common block</p> <p>Provide a brief description of relevant studies and effects. Information on the following aspects of behavior in soil can be described in this document; investigation of pH dependence of degradation based on field data, cross walk exercise to determine if a field study conducted in the US is relevant for the EU, comparison of field and laboratory DT50 values.</p> <p>Multiple endpoint summaries can be created where different DegT50 values are defined at different pH values. The pH should be specified in the 'Description of key information field.</p>	<p>Header 1</p>	<p>ENDPOINT_SUMMARY.F ieldStudies.Administrati veDataSummary</p>
<p>Additional information</p>	<p>Discussion(Header 1) – common block</p> <p>Table in the format specified in The list of Endpoints Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1) is recommended.</p>	<p>Header 1</p>	<p>ENDPOINT_SUMMARY.F ieldStudies.Discussion</p>

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	The EFSA DegT50Endpoint Selector excel file can be uploaded here.		
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Links to support material:

FOCUS Group (2006). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. (SANCO/ 10058/2005-v. 2.0, 434 pp Version 1.1, 18 December 2014)

EFSA European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., [doi:10.2903/j.efsa.2014.3662](https://doi.org/10.2903/j.efsa.2014.3662)

9.1.2 Route and rate of degradation in soil (field studies) – Endpoint study record

Purpose:

The soil dissipation studies shall provide estimates of the time required for dissipation of 50 % and 90 % (DisT50field and DisT90field) and, if possible, of the time required for degradation of 50 % and 90 % (DegT50field and DegT90field), of the active substance under field conditions. Where relevant, information on metabolites, breakdown and reaction products shall be provided.

Information on non-experimental studies e.g. comparison of extraction methods or soil storage stability can be reported in this endpoint study.

ENDPOINT_STUDY_RECORD.FieldStudies – v.6.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.Data Source
Materials and methods	Material and methods – common block In test guideline indicate according to which test guideline the study was conducted: US EPA, (2009) OCSPP 836.6100 Terrestrial	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods

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	<p>field dissipation document or OECD Guidance Document</p> <p>If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.</p> <p>Copy this block of fields for specifying more than one guideline.</p> <p>Applicable test guideline (guideline field): OECD Test Guideline 232: Guidance document for conducting pesticide terrestrial field dissipation studies.</p>		
Type of measurement	Indicate the type of measurement applied.	Multi-line text	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.TypeOfMeasurement
Media	Indicate the media investigated.	Multi-line text	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.Media
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>In this field, you can enter any information on materials and methods, for which no</p>	Header 2	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

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	<p>distinct field is available, or transfer free text from other databases.</p> <p>See Appendix A of EFSA guidance on the estimation of degradation rates Page 35 (DegT50matrix) from field experiments in the soil compartment EFSA (2014) You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>		
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.FieldStudies.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.OverallRemarksAttachments

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Kinetic evaluation	The filled "Template 7.1 - template for presentation of kinetic fitting" (https://doi.org/10.5281/zenodo.4557253) shall be uploaded here to report the the visual and statistical kinetic evaluation.	Attachments list	ENDPOINT_STUDY_RECORD.FieldStudies.Over allRemarksAttachments.KineticEvaluation
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.ApplicantSummaryAndConclusion

Links to support material:

FOCUS (1997). Soil persistence models and Eu registration

FOCUS (2006). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration (SANCO/ 10058/2005-v. 2.0, 434 pp Version 1.1, 18 December 2014).

EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2014.3662>

9.1.3 Mobility in the soil - Endpoint summary

Purpose:

Chemicals: conclude on the mobility and leaching potential of the active substance, metabolites, breakdown and reaction products

Microorganisms: Provide sufficient data to evaluate the mobility of the micro-organism and its degradation products in relevant environmental compartments.

Where studies are provided for more than one endpoint separate summaries can be created for each endpoint.

ENDPOINT_SUMMARY.OtherDistributionData – v.3.0 (Final) [July 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects.	Header 1	ENDPOINT_SUMMARY.OtherDistributionData.AdministrativeDataSummary

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<p>Additional information</p>	<p>Discussion (Header 1) – common block Provide additional information related to the endpoint. Presentation of the results in the tabular format of the List of Endpoints Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1) and Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3) is recommended</p> <p>If there is no additional information to be reported this field may be left empty.</p>	<p>Header 1</p>	<p>ENDPOINT_SUMMARY. OtherDistributionData.D iscussion</p>
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Links to support material:

Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)

9.1.3 Mobility in the soil - Endpoint study record

Purpose:

Chemicals/Microorganisms: Provide sufficient data to evaluate the mobility and leaching potential of metabolites, breakdown and reaction products.

ENDPOINT_STUDY_RECORD.OtherDistributionData -v.6.3 (Final) [September 2020]

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Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 312: Leaching in Soil Columns.	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods
Type of study	Include only information that does not fit into any of the specific chapters. Indicate the type of information, e.g. 'Soil leaching'. If not available from the picklist, use 'other:' and include an appropriate description. Include any relevant information from a study report or publication in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' or 'Overall remark' as appropriate. Fill in fields for Administrative data and Data source as appropriate.	Open list	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.TypeOfStudy
Media	Indicate the media addressed.	Open list	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.Media
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistribution

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			Data.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.ApplicantSummaryAndConclusion

Links to support material:

OECD Guidance Document 22: Guidance Document for the Performance Of Out-door Monolith Lysimeter Studies <https://doi.org/10.1787/20777876>

9.1.4 Estimation of concentrations in soil – Flexible summary

Purpose:

Chemical Product: PECsoil estimations shall relate both to a single application at the highest rate of application for which authorisation is sought, and to the maximum number at the shortest interval and highest rates of application for which authorisation is sought.

Initial PECsoil, immediately after application, shall be provided for the active substance and metabolites. Appropriate short-term and long-term PECsoil calculations (time weighted averages) shall be provided for the active substance and metabolites, with respect to data from ecotoxicological studies. Calculation of plateau concentrations in soil shall be provided where on the basis of soil dissipation studies it is established that Dist90 > one year, and where repeated application is envisaged, whether in the same growing season or in succeeding years.

It is possible to report both the active substance and metabolites in the same document. However it may be simpler to complete a template for a each substance. Information from multiple documents can be easily combined with report generator.

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FLEXIBLE_SUMMARY.EstConcSoil v1.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set.	Header 1	FLEXIBLE_SUMMARY.EstConcSoil.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.EstConcSoil.AdministrativeDataSummary.DataProtection
Link to relevant summary record(s)	Select the most relevant study(ies) or summary(ies).	Header 1	FLEXIBLE_SUMMARY.EstConcSoil.RelevantSummaries
Summaries used as input parameters		Endpoint reference list	FLEXIBLE_SUMMARY.EstConcSoil.RelevantSummaries.InputSummaries
Description of key information	Relevant studies from the active substance dataset can be referred to here	Header 1	FLEXIBLE_SUMMARY.EstConcSoil.KeyInformation
		Rich text area	FLEXIBLE_SUMMARY.EstConcSoil.KeyInformation.field357
PEC soil	Click on 'add new item' to repeat this block of fields for each relevant compound, representative use, and/or timing.	Header 1	FLEXIBLE_SUMMARY.EstConcSoil.PecSoil
Input parameters	Enter the input parameters. For example: - DT50 soil (days): - Kinetics: - Value: - Field or lab: - Plant uptake factor:	Rich text area	FLEXIBLE_SUMMARY.EstConcSoil.PecSoil.InputParameters
Agronomic input parameters	Enter the input parameters. For example: - Crop: - Depth of soil layer:	Rich text area	FLEXIBLE_SUMMARY.EstConcSoil.PecSoil.AgronomicInputParameters

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	<ul style="list-style-type: none"> - Soil bulk density: - % plant interception: - Number of applications: - Interval (d): - Application rate(s): g a.s./ha 		
PEC soil (mg/kg)			FLEXIBLE_SUMMARY.EstCo ncSoil.PecSoil.PecSoilMgkg
Use description	Select the GAP document/s for the use	Endpoint reference list	FLEXIBLE_SUMMARY.EstCo ncSoil.PecSoil.PecSoilMgkg. UseDescription
Parent / metabolite	Indicate whether the PEC is reported for the parent or the metabolite.	Closed list	FLEXIBLE_SUMMARY.EstCo ncSoil.PecSoil.PecSoilMgkg. ParentMetabolite
Substance	Select the substance for the PEC value.	Entity reference field	FLEXIBLE_SUMMARY.EstCo ncSoil.PecSoil.PecSoilMgkg. Substance
Timing	Report the time point for the PEC value e.g. initial, plateau concentration, short term, long term	Open list with remarks	FLEXIBLE_SUMMARY.EstCo ncSoil.PecSoil.PecSoilMgkg. Timing
Single application actual	Report the PEC concentration at the time point for a single application	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstCo ncSoil.PecSoil.PecSoilMgkg. SingleApplicationActual
Single application time weighted average	Report the time weighted average values for single application corresponding to the timing selected	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstCo ncSoil.PecSoil.PecSoilMgkg. SingleApplicationTimeWa
Multiple application actual	Report the PEC concentration at the time point for multiple applications	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstCo ncSoil.PecSoil.PecSoilMgkg. MultipleApplicationActual
Multiple application time weighted average	Report the time weighted average values for multiple applications corresponding to the timing selected	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstCo ncSoil.PecSoil.PecSoilMgkg. MultipleApplicationTimeWa
PEC soil (mg/kg)			
Additional information	Provide additional information related to the endpoint, for example: <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the 	Header 1	FLEXIBLE_SUMMARY.EstCo ncSoil.Discussion

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	<p>choice of the key study(ies) and the choice for the key value that characterises the endpoint</p> <ul style="list-style-type: none"> - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>		
	Provide any additional information related to the endpoint.	Rich text area	FLEXIBLE_SUMMARY.EstCo ncSoil.Discussion.Discussion
Attached background material	<p>Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.</p>		FLEXIBLE_SUMMARY.EstCo ncSoil.Discussion.AttachedB ackgroundMaterial
Attached document	<p>The original file only needs to be attached here if it differs from the non-confidential file uploaded under "Attached (sanitised) documents for publication". If a file is uploaded under this field a confidentiality claim must be submitted for each part of the file considered confidential.</p> <p>Reports on the models and calculation used to derive the PEC values can be uploaded here</p>	Single file attachment	FLEXIBLE_SUMMARY.EstCo ncSoil.Discussion.AttachedB ackgroundMaterial.Attached Document

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Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_SUMMARY.EstCo ncSoil.Discussion.AttachedB ackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.	Attachments list	FLEXIBLE_SUMMARY.EstCo ncSoil.Discussion.AttachedS anitisedDocsForPublication

Links to support material

FOCUS, 1997. Soil persistence models and EU registration. Report of the soil modelling work group, 29 February 1997, 77 pp.

European Commission, 2000. Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000).

FOCUS, 2006. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference SANCO/10058/2005-v. 2.0, 434 pp., as updated by the Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, v. 1.1, December 2014.

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9.2 Fate and behaviour in water and sediment

9.2.1 Aerobic mineralization in surface water – Endpoint summary

Purpose:

Summary information of the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.

Enter a short description of the most relevant endpoint data. The short description could include for example:

- the test guideline used,
- related conditions (e.g. temperature, a.s. concentration)
- test samples used
- rate of degradation
- pathway(s)
- measurement uncertainty if available;

ENDPOINT_SUMMARY.BiodegradationInWaterScreeningTests v.7.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BiodegradationInWaterScreeningTests.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.BiodegradationInWaterScreeningTests.KeyValueForChemicalSafetyAssessment
Biodegradation in water		Closed list	ENDPOINT_SUMMARY.BiodegradationInWaterScreeningTests.KeyValueForChemicalSafetyAssessment.BiodegradationInWater
Type of water	Choose the type of water of the most relevant study.	Open list	ENDPOINT_SUMMARY.BiodegradationInWaterScreeningTests.KeyValueForChemicalSafetyAssessment.TypeOfWater
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.BiodegradationInWaterScreeningTests.Discussion

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9.2.1 Aerobic mineralisation in surface water – Endpoint study record

Purpose:

The persistence and behaviour of plant protection products in open water (freshwater, estuarine and marine) shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.2.2.2 of Part A of the Annex to Regulation (EU) No 283/2013.

The test shall be reported unless the applicant shows that contamination of open water will not occur. The rate of degradation and the pathway or pathways shall be reported either for a 'pelagic' test system or for a 'suspended sediment' system. Where relevant, additional test systems, which differ with respect to organic carbon content, texture or pH shall be used.

Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and, where relevant, sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂ ;
- (c) volatile compounds other than CO₂ ;
- (d) individual identified transformation products;
- (e) extractable substances not identified; and
- (f) non-extractable residues in sediment.

The duration of the study shall not exceed 60 days unless the semi-continuous procedure with periodical renewal of the test suspension is applied. However, the period for the batch test may be extended to a maximum of 90 days, if the degradation of the test substance has started within the first 60 days.

ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests v.6.3 (Final)
[September 2020]

Name	Instructions	Data type	Field path	Containing Block name
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.AdministrativeData	Administrative data record block
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.Data Source	Data source block (Literature Reference)
Materials and methods	Material and methods – common block Applicable Test guideline: OECD Test Guideline 309:	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods	

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	<p>Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test</p> <p>ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment</p>			
Test material	<p>Test material – common block</p>	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.TestMaterials	Test materials block
Study design		Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign	
Oxygen conditions	<p>Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.OxygenConditions	
Inoculum or test system	<p>Select the inoculum used. As far as possible, indicate whether any activated sludge or sewage used was adapted or not. If the study report does</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.InoculumOrTestSystem	

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	<p>not give clear information thereof, select '..... (adaptation not specified)', e.g. 'sewage, domestic (adaptation not specified)'. In this case, give further explanation in field 'Details on inoculum', if any. In field 'Rationale for reliability', discuss the impact of this reporting deficiency on the study results. If no inoculum was added in the strictest sense, but natural water and/or sediment was used, indicate the corresponding test system, e.g. 'natural water / sediment'. Note that any simulation tests should be recorded using the corresponding template.</p>			
Details on inoculum	<p>Give details on inoculum as appropriate. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.DetailsOnInoculum	
Duration of test (contact time)	<p>Enter a single numeric value in the first numeric field if you select</p>	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.Mate	

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	no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		rialsAndMethods.StudyDesign.DurationOfTestContactTime	
Initial test substance concentration	Specify the initial test concentration applied. If different concentrations were used in different test runs, copy this block of fields accordingly. If a range of concentrations is reported, include the lower and upper values in the numeric range field. If appropriate copy this block of fields for indicating different parameters the initial concentration is based on (e.g. COD and test substance).		ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration	
Initial conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceCon	

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	the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		centration.InitialConcentration	
Based on	From drop-down list, select the parameter on which the initial concentration is based.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.BasedOn	
Initial test substance concentration				
Parameter followed for biodegradation estimation	Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as appropriate. In supplementary remarks field, give relevant details on the method. For radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.ParameterFollowedForBiodegradationEstimation	
Parameter followed for biodegradation estimation	Indicate the parameter used to measure biodegradation. Copy field for more than one	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.Param	

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	parameter as appropriate. In supplementary remarks field, give relevant details on the method. For radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.		eterFollowedForBiodegradationEstimation.ParameterFollowedForBiodegradationEstimation	
Parameter followed for biodegradation estimation				
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods	
Details on study design	Use freetext template and delete/add elements as	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.Mate	

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	appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		rialsAndMethods.StudyDesign.DetailsOnStudyDesign	
Reference substance	Indicate identity of reference substance(s) used and give details in the supplementary remarks field as appropriate. Repeat field for each substance.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.ReferenceSubstance	
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables	Any other information on materials and methods incl. tables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion	
Preliminary study	Describe relevant results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.PrelimStudyRs	
Test performance	Report on any unusual observations during test or any other information affecting results. Give reasons for	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.TestPerformance	

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	<p>any rejection of the test results if applicable. Note that any deviations from test procedure should be briefly stated in field 'Deviations from guideline'.</p>			
% Degradation	<p>Indicate percentage of degradation of test substance including standard deviation at the end of the study period. Indicate the parameter the percentage is based on and the sampling time. Copy this block of fields for recording the percentage values for different parameters. Note that the degradation at different sampling time points (raw data) should be recorded in below field 'Details on results'. Note: BOD*100/COD results should be entered in the respective fields below. Note: In the case of QSAR/QSPR results, the parameter</p>		<p>ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation</p>	

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	'probability of ready biodegradability (QSAR)', 'calculated rating of total degradation time (QSAR/QSPR)' or 'half-life in days (QSAR/QSPR)' can be selected if applicable, and the relevant value entered in field 'Value'.			
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.KeyResult	
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.Parameter	
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.Degr	

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	numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.			
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.StDev	
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.SamplingTime	
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.RemarksOnResults	

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% Degradation				
<p>Details on results</p>	<p>Record the degradation / elimination kinetics for the different types of test suspensions, i.e. percentage of degradation at different sampling time points. For robust study summaries or as requested by the regulatory programme, include table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). In field 'Attached background material', attach graph(s) with the full degradation or elimination curves for the test and reference substances, the lag phase, degradation phase, the 10-d window and slope. For tests for ready</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.ResultsDetails</p>	

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	<p>biodegradability, in which oxygen consumption is used as analytical method (e.g. MITI method), a BOD curve against time should be attached. If requested by the regulatory programme, also include a table on the material (mass) balance of parent compound and transformation products and a table showing the percentage data for degradability measured as BOD, DOC and by specific chemical analysis (see predefined tables).</p>			
BOD5 / COD results	<p>For BOD5 tests, copy this block of fields for entering BOD5 and COD values (or ranges if reported so) including the unit, and the ratio $BOD5 \times 100 / COD$ (with no unit). If a BOD5/COD or BOD5/ThOD ratio is reported, multiply the original value by 100. Include any raw data in field 'Any</p>	Header 2	<p>ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults</p>	

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	other information on results incl. tables'.			
BOD5 / COD	For BOD5 tests, copy this block of fields for entering BOD5 and COD values (or ranges if reported so) including the unit, and the ratio BOD5*100/COD (with no unit). If a BOD5/COD ratio is reported, multiply the original value by 100. Include any raw data in field 'Any other information on results incl. tables'.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod.KeyResult	
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod.Parameter	

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Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod.Value	
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod.RemarksOnResults	
BOD5 / COD				
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Re	

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			sultsWithReferenceSubstance	
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables	Any other information on results incl. tables Block
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.OverallRemarksAttachments	Overall remarks, attachments block
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ApplicantSummaryAndConclusion	Applicant's summary and conclusion block

9.2.2 Biodegradation in water, sediment and surface water

Biodegradation in water and sediment: simulation tests (EU PPP) – Endpoint summary

Purpose:

Information should be reported on:

Chemicals: identify and characterise the components present, establish the relative proportions of the components (mass balance). The degradation pathway or pathways shall be reported for two water/sediment systems. The two sediments selected shall differ with respect to organic carbon content and texture, and where relevant, with respect to pH. Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and sediment as a function of time

Microorganisms: viability/population dynamics in natural sediment/water systems under both dark and illuminated conditions.

ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests v.7.4			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationIn

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			WaterAndSedimentSimulationTests.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems Method C.4 Determination of "ready" biodegradability (Annex to Regulation (EC) No 440/2008) OECD Guideline Test 301: Ready Biodegradability (301 A - F) OECD Test Guideline 310: Ready Biodegradability - CO ₂ in sealed vessels (Headspace Test) Microbial Pesticide Test Guidelines OPPTS	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods

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	885.5300 Expression in a Freshwater Environment		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign
Oxygen conditions	Indicate whether test was performed under aerobic or anaerobic conditions. Select 'aerobic/anaerobic' if both oxygen conditions occur as in water/sediment studies. If 'aerobic (low dissolved oxygen)' applies, specify in the supplementary remarks field or in the field 'Details on study design' that the O ₂	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.OxygenConditions

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	concentration was controlled. Include any explanations in the supplementary remarks field as appropriate.		
Inoculum or test system	<p>Select the inoculum used. As far as possible, indicate whether any activated sludge or sewage used was adapted or not. If the study report does not give clear information thereof, select '..... (adaptation not specified)', e.g. 'sewage, domestic (adaptation not specified)'. In this case, give further explanation in field 'Details on inoculum', if any. In field 'Rationale for reliability', discuss the impact of this reporting deficiency on the study results.</p> <p>If no inoculum was added in the strictest sense, but natural water and/or sediment was used, indicate the corresponding test system, e.g. 'natural water / sediment'. Note that any simulation tests should be recorded using the corresponding template.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.InoculumOrTestSystem
Details on source and properties of surface water	Give details on source and properties of surface water used as inoculum if applicable. Use freetext template and delete/add	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnSourceAndP

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	elements as appropriate.		propertiesOfSurfaceWater
Details on source and properties of sediment	Give details on source and properties of sediment used as inoculum if applicable. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnSourceAndPropertiesOfSediment
Details on inoculum	Give details on any other inoculum, e.g. wastewater, activated sludge, anaerobic sludge if applicable. Use either freetext template 1 (activated sludge) or 2 (other) and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnInoculum
Duration of test (contact time)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime
Initial test substance concentration	Specify the initial test concentration applied. If different concentrations were used in different test runs, copy this block of fields accordingly. If a range of concentrations is reported, include the lower and upper values in the numeric range field. If appropriate copy this		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration

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	block of fields for indicating different parameters the initial concentration is based on (e.g. COD and test substance).		
Initial conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.InitialConcentration
Based on	From drop-down list, select the parameter on which the initial concentration is based.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.BasedOn
Initial test substance concentration			
Parameter followed for biodegradation estimation	Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as appropriate. In the supplementary remarks field, give relevant details on the method. Indicate if total mineralisation was determined if applicable. Specify if the radioactivity was recovered as parent and/or metabolite or associated with biomass. For further	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.ParameterFollowedForBiodegradationEstimation

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	relevant details on radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.		
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products and/or non-extractable residues. Specify methods for water and sediment if applicable.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods
Details on study design	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnStudyDesign
Reference substance	Indicate identity of reference substance(s) used and give details in the supplementary remarks field as appropriate. Repeat field for each substance.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.ReferenceSubstance

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Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion
Test performance	Report on any unusual observations during test or any other information affecting results. Give reasons for any rejection of the test results if applicable. Note that any deviations from test procedure should be briefly stated in field 'Deviations from guideline'.	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.TestPerformance
Mean total recovery	If applicable, indicate mean total recovery of test material as percentage of applied amount in water and/or sediment +/- standard deviation. If relevant, also specify 'Total recovery in abiotic control measured at end of test' and 'Total recovery in biologically active treatment at end of test'.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery
Compartment	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.Compartment

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Sampling date		Date	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.MeanTotalR ecovery.SamplingDate
% Total extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.MeanTotalR ecovery.TotalExtractabl e
% Non extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.MeanTotalR ecovery.NonExtractable
% CO2	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.MeanTotalR ecovery.CO2
% Other volatiles	Enter a single numeric value in the first numeric field if you select no qualifier or	Range (Decimal)	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd

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	'>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		Discussion.MeanTotalRecovery.OtherVolatiles
% Recovery	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.Recovery
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.StDev
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.RemarksOnResults
Mean total recovery			
% Degradation	Indicate percentage of degradation of test substance including standard deviation at the end of the study period. Indicate the		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation

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	parameter the percentage is based on and the sampling time. Copy this block of fields for recording the percentage values for different parameters. Note that the degradation at different sampling time points (raw data) should be recorded in below field 'Details on results'.		
Parent/product	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.ParentProduct
Name or code for product	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.NameOrCodeForProduct
Compartment	Select from drop-down list.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.Compartment
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.KeyResult
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.Degr

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	field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.StDev
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.Parameter
Sampling date	Enter a date (yyyy-mm-dd).	Date	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.SamplingDate
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.SamplingTime
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.RemarksOnResults

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	supplementary remarks field; or - entering any additional information by selecting 'other:'		
% Degradation			
Half-life of parent compound / 50% disappearance time (DT50)	Include value (or range if reported so) of half-life and indicate the type of half-life (For first order kinetics DT50 = half-life). For water-sediment systems repeat this block of fields for each compartment.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.KeyResult
Compartment	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.Compartment
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.HalfLife
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationIn

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			WaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.StDev
Type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.Type
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.Temp
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.RemarksOnResults
Half-life of parent compound / 50% disappearance time (DT50)			
Mineralization rate (in CO2)	Enter Mineralization rate (in CO2)	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationIn

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			WaterAndSedimentSimulationTests.ResultsAndDiscussion.MineralizationRateInCO2
Other kinetic parameters	Include any other relevant kinetic parameters if applicable. Select the respective item(s) from the multi-select picklist and include the value in the associated remarks field.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.OtherKineticParameters
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'. Not relevant for microorganisms	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAnd

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	from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.		Discussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on transformation products	Indicate any relevant supplementary information on transformation products. Use freetext template and delete/add items as appropriate. If useful attach a figure in the corresponding field.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.TransfProductsDetails
Evaporation of parent compound	Indicate whether evaporation of the parent compound occurred or not. Include any explanations in field 'Details on results' as appropriate. 'Yes' should be selected when CO ₂ has been detected in volatile traps	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.EvaporationOfParentCompound

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Volatile metabolites	Indicate whether volatile metabolites were found or not. Include any explanations in field 'Details on results' as appropriate.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.VolatileMetabolites
Residues	Indicate whether residues were found or not. Include any explanations in field 'Details on results' as appropriate.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Residues
Details on results	Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). In field 'Attached background material', attach graph(s) with the full degradation or elimination curves. TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.DetailsOnResults

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	<p>encountered. MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table.</p> <p>STERILE TREATMENTS: If used, report the transformation of the parent, and compare the results with those of the non-sterile treatments:</p> <p>SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.</p>		
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.ResultsWithReferenceSubstance
Any other information on results incl. tables	<p>Any other information on results incl. tables Block</p> <p>For Microorganisms the tables in the results and discussion section do not need to reported</p>	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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	<p>unless suitable data is available. However Tabulation/graphs of population dynamics and Discussion of test results should be provided in this field.</p>		
Overall remarks, attachments	<p>Overall remarks, attachments – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be uploaded in Attached document only if it differs from the sanitised version</p>	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.OverallRemarksAttachments
Kinetic evaluation	<p>The filled "Template 7.1 - template for presentation of kinetic fitting" (https://doi.org/10.5281/zenodo.4557253) shall be uploaded here to report the the visual and statistical kinetic evaluation.</p>	Attachment (multiple)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.OverallRemarksAttachments.KineticEvaluation
Applicant's summary and conclusion	<p>Applicants summary and conclusion – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ApplicantSummaryAndConclusion
Validity criteria	<p>Include any validity criteria from the followed study guidance.</p>		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ApplicantSummaryAndConclusion.ValidityCriteria
Validity criteria	<p>Type in the addressed validity criteria.</p>	Text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSim

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			ulationTests.ApplicantSummaryAndConclusion.ValidityCriteria.ValidityCriteria
Observed value	Type in the observation related to the respective validity criteria.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ApplicantSummaryAndConclusion.ValidityCriteria.ObservedValue

Route of biodegradation in water, sediment and surface water – Endpoint summary

Purpose:

Chemical: To conclude on the persistence of the active substance or product in aquatic systems. Derivation of DT50, DT90, Kinetic parameters and formation fraction in water, sediment or the whole system from the submitted endpoint studies.

The following endpoints are covered by this summary document: Water/sediment study, Irradiated water/sediment study.

ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP v1.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa
Persistence / rate of degradation in freshwater	Report persistence endpoints for parent compound and metabolites in the water column.		ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater

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Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.Substance
pH	Enter the pH value of the water phase in the laboratory test system.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.pH
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the pH was measured.	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.MeasuredIn
Half-life in freshwater	Enter the DT50 value for persistence in the water column.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.HalfLifeFreshWater
DT90 in freshwater	Enter the DT90 value for persistence in the water column.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.DtNinetyFreshwater

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at the temperature of	Enter the temperature of the test system in the laboratory.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.Temperature
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for persistence.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP,HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.Precursor

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Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.Remarks
Persistence / rate of degradation in freshwater			
Modelled rate of degradation in freshwater	Report modelling endpoints for parent compound and metabolites in the water column. Note that modelling endpoints are not routinely completed for the water column.		ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.Substance
pH	Enter the pH value of the water phase in the laboratory test system.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the water pH was measured.	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegr

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			adationFreshwater.MeasuredIn
Normalised (DT50)	Enter the DT50 value in water column for modelling at 20°C, normalized using a Q10 of 2.58.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.NormalisedDtFifty
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for modelling.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.ChiSquare
Method of calculation	For normalised DT50 (modelling endpoint), when biphasic kinetic is used, it should be specified how the DT50 was derived (DT90FOMC/3.32, DFOP slow phase, etc.)	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegr

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			adationFreshwater.Pre cursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.Remarks
Modelled rate of degradation in freshwater	Rate of degradation in marine water is not relevant for PPP authorization.		
Rate of degradation in marine water	Rate of degradation in marine water is not relevant for PPP authorization.	Header 2	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater
Half-life in marine water		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.HalfLifeMarineWater
at the temperature of	Enter the temperature of the test system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.Temperature
Persistence / rate of degradation in freshwater sediment	Report persistence endpoints for parent compound and metabolites in the sediment.		ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulati

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			onTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.Substance
pH	Enter the pH value of the sediment in the laboratory test system.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the sediment pH was measured.	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.MeasuredIn
Half-life in freshwater sediment	Enter the DT50 value for persistence in sediment.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.HalfLifeFreshwaterSediment
DT90 in freshwater sediment	Enter the DT90 value for persistence in sediment.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyV

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			alueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.DTNinetyFreshwaterSediment
at the temperature of	Enter the temperature of the test system in the laboratory.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.Temperature
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP,HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulation

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			onTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.Precursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.Remarks
Persistence / rate of degradation in freshwater sediment	Report half-life and related measurements for sediment		
Modelled rate of degradation in freshwater sediment	Report modelling endpoints for parent compound and metabolites in the sediment. Note that modelling endpoints are not routinely completed for the sediment.		ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWater

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			rAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.Substance
pH	Enter the pH value of the sediment in the laboratory test system	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the sediment pH was measured.	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.MeasuredIn
Normalised (DT50)	Enter the DT50 value for modelling at 20°C, normalized using a Q10 of 2.58.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.NormalisedDtFifty
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.ChiSquare
Method of calculation	For normalised DT50 (modelling endpoint), when biphasic kinetic is used, it should be specified how the DT50 was derived	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationM

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	(DT90FOMC/3.32, DFOP slow phase, etc.)		arineWater.ModelledDegradationFreshwaterSed.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.Precursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.Remarks
Modelled rate of degradation in freshwater sediment			
Rate of degradation in marine water sediment	Rate of degradation in marine water sediment is not relevant for PPP authorization.	Header 2	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyV

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			alueCsa.DegradationMarineSediment
Half-life in marine water sediment		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.HalfLifeMarineWaterSed
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.Temperature
Persistence / rate of degradation in whole system	Report persistence endpoints for parent compound and metabolites in the whole system.		ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.Substance
pH		Decimal	ENDPOINT_SUMMARY .BiodegradationInWater

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			rAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water).	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.MeasuredIn
Half-life in freshwater	Enter the DT50 value for persistence in the whole system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.HalfLifeFreshWater
DT90 in freshwater	Enter the DT90 value for persistence in the whole system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.DtNinetyFreshwater
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.Temperature
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.ChiSquare

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	model (reported in the field "Method of calculation") used for deriving the degradation rates for persistence.		onTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.Precursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulation

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			onTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.Remarks
Persistence / rate of degradation in whole system	Report half-life and related measurements for the whole system		
Modelled rate of degradation in whole system	Report modelling endpoints for parent compound and metabolites in the whole system.		ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.Substance
pH		Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water).	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulation

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			onTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.MeasuredIn
Normalised (DT50)	Enter the DT50 value in whole system for modelling at 20°C, normalized using a Q10 of 2.58.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.NormalisedDtFifty
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for modelling.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.ChiSquare
Method of calculation	For normalised DT50 (modelling endpoint), when biphasic kinetic is used, it should be specified how the DT50 was derived (DT90FOMC/3.32, DFOP slow phase, etc.)	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulation

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			onTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.Precursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.Remarks
Modelled rate of degradation in whole system			
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.Discussion

Links to support material:

FOCUS, 2006. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference SANCO/10058/2005-v. 2.0, 434 pp., as updated by the Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, v. 1.1, December 2014.

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Route and rate of biodegradation in water, sediment and surface water - Endpoint study record

Purpose:

Chemical: Conclude on the route of degradation of the active substance or product. Derivation of the proportion and the maximum occurrence of components considering the submitted endpoint studies

ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP v1.2 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a
Route of degradation in freshwater			ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.Substance
pH	Measured in e.g. calcium chloride solution, water.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.Ph
Mineralisation (%)	Percent mineralisation after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.Mineralisation
Non extractable residues (%)	Percent non-extractable residues after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.MaximumOccurrence

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Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.DayMaximumOccurrence
Actual duration (days)	Report the duration of the study in days.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.ActualDuration
Radio label	Provide information on the radio labelling used to obtain these results	Text	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.RadioLabel
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.Remarks
Route of degradation in freshwater			
Route of degradation in marine water			ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.Substance
pH	Measured in e.g. calcium chloride solution, water.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.Ph
Mineralisation (%)	Percent mineralisation after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.Mineralisation
Non extractable residues (%)	Percent non-extractable residues after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days)	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.MaximumOccurrence

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	observed in the parent-dosed study.		
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.DayMaximumOccurrence
Actual duration (days)		Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.ActualDuration
Radio label		Text	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.RadioLabel
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.Remarks
Route of degradation in marine water			
Route of degradation in freshwater sediment			ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.Substance
pH	Measured in e.g. calcium chloride solution, water.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.Ph
Mineralisation (%)	Percent mineralisation after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.Mineralisation
Non extractable residues (%)	Percent non-extractable residues after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.NonExtractableResidues

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Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.MaximumOccurrence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.DayMaximumOccurrence
Actual duration (days)		Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.ActualDuration
Radio label		Text	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.RadioLabel
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.Remarks
Route of degradation in freshwater sediment			
Route of degradation in marine water sediment			ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.Substance
pH	Measured in e.g. calcium chloride solution, water.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.Ph
Mineralisation (%)	Percent mineralisation after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.Mineralisation

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Non extractable residues (%)	Percent non-extractable residues after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.MaximumOccurrence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.DayMaximumOccurrence
Actual duration (days)		Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.ActualDuration
Radio label		Text	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.RadioLabel
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.Remarks
Route of degradation in marine water sediment			
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.Discussion
Attached (sanitised) documents for publication	A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential	Attachments list	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.Discussion.AttachedSanitisedDocsForPublication

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	<p>should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.</p> <p>For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section.</p>		
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Links to support material:

ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment (revision 3, June 2017)

DG SANCO Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides" (25.09.2012 – rev. 3)

9.2.4 Estimation of concentrations in groundwater – Flexible summary

Purpose:

Chemical Product: The groundwater contamination routes shall be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions. PEC Groundwater estimations shall relate to the maximum number and highest rates of application, at the shortest interval, and to the time of application for which authorisation is sought.

FLEXIBLE_SUMMARY.EstConcGroundwater v1.2 (Final)

Name	Instructions	Data type	Field path
Administrative data	The general rules on confidentiality requests apply in setting the flags (Administrative	Header 1	FLEXIBLE_SUMMARY.EstConcGroundwater.AdministrativeDataSummary

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	data summary – common block . See section on Confidentiality of dossiers		
		Confidentiality	FLEXIBLE_SUMMARY.EstConcGroundwater.AdministrativeDataSummary.DataProtection
Link to relevant summary record(s)	Select the most relevant study(ies) or summary(ies).	Header 1	FLEXIBLE_SUMMARY.EstConcGroundwater.RelevantSummaries
Summaries used as input parameters		Endpoint reference list	FLEXIBLE_SUMMARY.EstConcGroundwater.RelevantSummaries.InputSummaries
Description of key information		Header 1	FLEXIBLE_SUMMARY.EstConcGroundwater.KeyInformation
	Relevant studies from the active substance dataset can be referred to here	Rich text area	FLEXIBLE_SUMMARY.EstConcGroundwater.KeyInformation.field357
PEC ground water		Header 1	FLEXIBLE_SUMMARY.EstConcGroundwater.PecGroundWater
Input parameters in FOCUS ground water	Enter the input parameters. For example: <ul style="list-style-type: none"> - Model(s) used: - Water solubility (mg/L): - Vapour pressure (Pa at 20°C): - Molecular weight: - Geometric mean DT50: - KOC (mL/g): - 1/n: - ff (from parent): 	Rich text area	FLEXIBLE_SUMMARY.EstConcGroundwater.PecGroundWater.InputParametersFocusGroundWater
Agronomic input parameters	Enter the input parameters. For example: <ul style="list-style-type: none"> - Gross application rate (g a.s./ha): - Crop growth stage: 	Rich text area	FLEXIBLE_SUMMARY.EstConcGroundwater.PecGroundWater.AgronomicInputParameters

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	<ul style="list-style-type: none"> - Crops: - Crop uptake factor: - Canopy interception (%): - Application rate net of interception (g a.s./ha): - Number of applications: - Application interval (d): - Time of application: - Plant uptake factor: 		
PEC ground water	Click on 'add new item' to repeat this block of fields to add PECgw for each relevant compound, tier, model used and scenario.		FLEXIBLE_SUMMARY.EstConcGro undwater.PecGroundWater.PecGroundWater
Use description	Select the GAP document/s for the use	Endpoint reference list	FLEXIBLE_SUMMARY.EstConcGro undwater.PecGroundWater.PecGroundWater.UseDescription
Parent / metabolite	Indicate whether the PEC is reported for the parent or the metabolite.	Closed list	FLEXIBLE_SUMMARY.EstConcGro undwater.PecGroundWater.PecGroundWater.ParentMetabolite
Substance	Select the substance for the PEC value.	Entity reference field	FLEXIBLE_SUMMARY.EstConcGro undwater.PecGroundWater.PecGroundWater.Substance
Tier		Text	FLEXIBLE_SUMMARY.EstConcGro undwater.PecGroundWater.PecGroundWater.Tier
Model	Select the model used to calculate the PECgroundwater (e.g. PEARL, PELMO, etc...).	Open list with remarks	FLEXIBLE_SUMMARY.EstConcGro undwater.PecGroundWater.PecGroundWater.Model
Scenario	Select the scenario (e.g. Porto, Hamburg, etc...).	Open list with remarks	FLEXIBLE_SUMMARY.EstConcGro undwater.PecGroundWater.PecGroundWater.Scenario

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PECgw	Report the estimated concentration in micrograms/Litre	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcGro undwater.PecGroundWater.PecGroundWater.Pecgw
PEC ground water			
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Header 1	FLEXIBLE_SUMMARY.EstConcGro undwater.Discussion
	Provide any additional information related to the endpoint.	Rich text area	FLEXIBLE_SUMMARY.EstConcGro undwater.Discussion.Discussion
Attached background material	Attach any background document that		FLEXIBLE_SUMMARY.EstConcGro undwater.Discussion.AttachedBackgroundMaterial

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	cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.		
Attached document	The original file only needs to be attached here if it differs from the non-confidential file uploaded under "Attached (sanitised) documents for publication". If a file is uploaded under this field a confidentiality claim must be submitted for each part of the file considered confidential.	Single file attachment	FLEXIBLE_SUMMARY.EstConcGro undwater.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_SUMMARY.EstConcGro undwater.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A non-confidential version of any submitted background material must be uploaded here. These will be	Attachments list	FLEXIBLE_SUMMARY.EstConcGro undwater.Discussion.AttachedSanitisedDocsForPublication

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	<p>published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.</p> <p>Reports on the models and calculation used to derive the PEC values can be uploaded here</p>		
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Links to support material:

European Commission, 2014. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Workgroup. EC Document Reference SANCO/13144/2010-v. 3,613 pp., as outlined in Generic guidance for tier 1 FOCUS groundwater assessment, v. 2.2, May 2014.

FOCUS, 2006. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference SANCO/10058/2005-v. 2.0, 434 pp., as updated by the Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, v. 1.1, December 2014.

9.2.5 Estimation of concentrations in surface water and sediment – Flexible summary

Purpose:

Chemical Product: The surface water and sediment contamination routes shall be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions. Suitable estimations (calculations) of predicted environmental concentration in surface water PECSW and sediment PECSW of active substance shall be submitted, unless the applicant shows that contamination will not occur. PECSW and PECSW estimations shall relate to the maximum number and highest rates of application, at the shortest interval, for which authorisation is sought, and be relevant to ditches, ponds, and streams.

It is possible to report both the active substance and metabolites in the same document. However it may be simpler to complete a template for a each substance. Information from multiple documents can be easily combined with report generator.

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FLEXIBLE_SUMMARY.EstConcWaterSed v1.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set.	Header 1	FLEXIBLE_SUMMARY.EstConcWaterSed.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.EstConcWaterSed.AdministrativeDataSummary.DataProtection
Link to relevant summary record(s)	Select the most relevant study(ies) or summary(ies).	Header 1	FLEXIBLE_SUMMARY.EstConcWaterSed.RelevantSummaries
Summaries used as input parameters		Endpoint reference list	FLEXIBLE_SUMMARY.EstConcWaterSed.RelevantSummaries.InputSummaries
Description of key information		Header 1	FLEXIBLE_SUMMARY.EstConcWaterSed.KeyInformation
	Relevant studies from the active substance dataset can be referred to here	Rich text area	FLEXIBLE_SUMMARY.EstConcWaterSed.KeyInformation.field357
PEC surface water, PEC sediment		Header 1	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment

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<p>Input parameters in FOCUS step 1 and 2</p>	<p>Enter the input parameters. For example:</p> <ul style="list-style-type: none"> - Version control no. of FOCUS calculator: Steps 1&2 v3.2 - Molecular weight (g/mol): 274.15 - KOC (mL/g): 381.5 (geomean) - DT50 soil (d): 100 days (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7) - DT50 water/sediment system (d): 39.6 d (geomean from sediment water studies) - DT50 water (d): 39.6 d - DT50 sediment (d): 1000 d - Crop interception (%): no interception 	<p>Rich text area</p>	<p>FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwo</p>
<p>Input parameters in FOCUS step 3</p>	<p>Enter the input parameters. For example:</p> <ul style="list-style-type: none"> - Control no. of FOCUS software - Molecular weight (g/mol) - Water solubility (mg/L) - Vapour pressure (Pa at 20°C) - KOM/KOC (mL/g) - 1/n - Q10 - Crop uptake factor - DT50 soil 	<p>Rich text area</p>	<p>FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThree</p>

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	<ul style="list-style-type: none"> - DT50 water - DT50 sediment - DT50 foliar - Washoff coefficient 		
Agronomic input parameters	<p>Enter the input parameters. For example:</p> <ul style="list-style-type: none"> - Crop and growth stage - Number of applications - Interval (d) - Application rate (g a.s./ha) - Application window Step 1 and 2 - Application window Step 3 	Rich text area	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.AgroInputParameters
Input parameters in FOCUS step 4	<p>Enter the input parameters. For example:</p> <ul style="list-style-type: none"> - Version control no. of FOCUS software - Deposition due to volatilisation - Risk mitigation measures, if necessary - Buffer zone (m) - Vegetated filter strip (m) - Drift reducing nozzles (%) 	Rich text area	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.IinputParamFocusFour
FOCUS step 1 and 2	<p>Click on 'add new item' to repeat this block of fields to add PECsw, PECsed for each relevant use, compound, and Step.</p>		FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList
Use description	<p>Link to the use description considered when deriving the PEC values</p>	Endpoint reference list	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.UseDescription

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Parent / metabolite	Indicate whether the PEC is reported for the parent or the metabolite.	Closed list	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.ParentMetabolite
Substance	Select the substance for the PEC value.	Entity reference field	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.Substance
Step	Indicate whether the results are for step 1 or 2 and the region	Open list with remarks	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.Step
Day after overall maximum	Report the timepoint for the PEC value	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.DayAfterOverallMaximum
Max PEC_{sw}	Report the Actual PEC for surface water	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.MaxPecsw
TWA PEC_{sw}	Report the Time Weighted Average PEC value for surface water	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.TwaPecsw
Max PEC_{sed}	Report the Actual PEC for sediment	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.ActualPecsed
TWA PEC_{sed}	Report the Time Weighted Average PEC value for sediment	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.TwaPecsed
Remarks		Text area	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepOneTwoList.Remarks
FOCUS step 1 and 2			
FOCUS step 3	Click on 'add new item' to repeat this block of fields to add PEC _{sw} and PEC _{sed} for each relevant use, compound, scenario, and water body.		FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList
Use description	Link to the use description considered when deriving the PEC values	Endpoint reference list	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.UseDescription

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Parent / metabolite	Indicate whether the PEC is reported for the parent or the metabolite.	Closed list	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.ParentMetabolite
Substance	Select the substance for the PEC value.	Entity reference field	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.Substance
Focus scenario	Select the relevant FOCUS scenario e.g. D1	Open list with remarks	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.FocusScenario
Dominant route of entry	Select the dominant route of entry e.g. runoff	Open list with remarks	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.DominantRouteOfEntry
Water body	Select the water body e.g. stream	Open list with remarks	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.WaterBody
Day after overall maximum	Report the timepoint for the PEC value	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.DayAfterOverallMaximum
Max PEC_{sw}	Report the Actual PEC for surface water	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.MaxPecsw
TWA PEC_{sw}	Report the Time Weighted Average PEC value for surface water	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.TwaPecsw
Max PEC_{sed}	Report the Actual PEC for sediment	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.ActualPecsed
TWA PEC_{sed}	Report the Time Weighted Average PEC value for sediment	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.TwaPecsed
Remarks		Text area	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepThreeList.Remarks
FOCUS step 3	Click on 'add new item' to repeat this block of fields to add PEC _{sw} and PEC _{sed} for each relevant use, compound, scenario, and water body		

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FOCUS step 4			FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour
Use description	Link to the use description considered when deriving the PEC values	Endpoint reference list	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.UseDescription
Parent / metabolite	Indicate whether the PEC is reported for the parent or the metabolite.	Closed list	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.ParentMetabolite
Substance	Select the substance for the PEC value.	Entity reference field	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.Substance
Focus scenario	Select the relevant FOCUS scenario e.g. D1	Open list with remarks	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.FocusScenario
Water body	Select the water body e.g. stream	Open list with remarks	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.WaterBody
Risk mitigation measures	Select the risk mitigation measure considered when estimating the PEC value e.g. drift reducing nozzles	Open list with remarks	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.RiskMitigationMeasures
Max PEC_{sw}	Report the Actual PEC for surface water	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.MaxPecsw
TWA PEC_{sw}	Report the Time Weighted Average PEC value for surface water	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.TwaPecsw
Max PEC_{sed}	Report the Actual PEC for sediment	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.ActualPecsed
TWA PEC_{sed}	Report the Time Weighted Average PEC value for sediment	Half-bounded with closed list (Decimal)	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.TwaPecsed
Remarks		Text area	FLEXIBLE_SUMMARY.EstConcWaterSed.PecSurfaceWaterPecSediment.FocusStepFour.Remarks
FOCUS step 4			

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<p>Additional information</p>	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	<p>Header 1</p>	<p>FLEXIBLE_SUMMARY.EstConcWater Sed.Discussion</p>
	<p>Provide any additional information related to the endpoint.</p>	<p>Rich text area</p>	<p>FLEXIBLE_SUMMARY.EstConcWater Sed.Discussion.Discussion</p>
<p>Attached background material</p>	<p>Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of</p>		<p>FLEXIBLE_SUMMARY.EstConcWater Sed.Discussion.AttachedBackground Material</p>

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	fields for attaching more than one file.		
Attached document	The original file only needs to be attached here if it differs from the non-confidential file uploaded under "Attached (sanitised) documents for publication". If a file is uploaded under this field a confidentiality claim must be submitted for each part of the file considered confidential.	Single file attachment	FLEXIBLE_SUMMARY.EstConcWater Sed.Discussion.AttachedBackground Material.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_SUMMARY.EstConcWater Sed.Discussion.AttachedBackground Material.Remarks
Attached background material			
Attached (sanitised) documents for publication	A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the	Attachments list	FLEXIBLE_SUMMARY.EstConcWater Sed.Discussion.AttachedSanitisedDocumentsForPublication

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	<p>redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.</p> <p>Reports on the models and calculations used to derive the PEC values can be uploaded here</p>		
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Links to support material:

FOCUS Group (2014). Generic Guidance for FOCUS Surface Water Scenarios. Version 1.4, May 2015
 FOCUS Group (2014). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Version 1.1, 18 December 2014

Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration - Final Report of the Work Group on Degradation Kinetics of FOCUS (Sanco/10058/2005, version 2.0, June 2006)

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9.3 Fate and behaviour in air

9.3.1 Route and rate of degradation in air - Endpoint summary

Purpose

Provide summary information of the most relevant study(-ies) from which the key value for assessment is extrapolated. Provide only the most relevant details related to the concentrations in air.

ENDPOINT_SUMMARY.PhototransformationInAir v.5.0			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block Conclude on direct photolysis in air, photochemical oxidative degradation in air and volatilization For microorganisms indicate if concentration in air are observed	Header 1	ENDPOINT_SUMMARY.Photo transformationInAir.AdministrativeDataSummary
Key value for chemical safety assessment	Only to be completed if such data exists	Header 1	ENDPOINT_SUMMARY.Photo transformationInAir.KeyValueForChemicalSafetyAssessment
Half-life in air		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Photo transformationInAir.KeyValueForChemicalSafetyAssessment.HalfLifeInAir
Degradation rate constant with OH radicals		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Photo transformationInAir.KeyValueForChemicalSafetyAssessment.DegradationRateConstantWithOHRadicals
Additional information	Discussion (Header 1) – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_SUMMARY.Photo transformationInAir.Discussion

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Links to support material:

Pesticides in Air: Considerations for Exposure Assessment”. Report of the FOCUS Working Group on Pesticides in Air (SANCO/10553/2006 Rev 2 June 2008)

https://esdac.jrc.ec.europa.eu/public_path/projects_data/focus/air/docs/FOCUS_AIR_GROUP_REPORT-FINAL.pdf

9.3.1 Route and rate of degradation in air - Endpoint study record

Purpose

Chemicals: An estimate of the half-life in the upper atmosphere of the active substance and any volatile metabolites, breakdown and reaction products, formed in soil or natural water systems, shall be calculated and reported.

Estimates of active substance upper atmospheric half-lives, based on monitoring data shall also be calculated, when monitoring data that enable this to be done, are available.

Microorganisms: In case of particular concerns for operator, worker or bystander exposure, information on the concentrations in air might be necessary.

ENDPOINT_STUDY_RECORD.PhototransformationInAir v.7.3			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.AdministrativeData
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.PhototransformationInAir.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAn

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			dMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Study design		Header 2	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign
Estimation method (if used)	If the photodegradation was estimated, e.g. the photochemical reaction with OH radicals, include details on the computational method used. Use freetext template as appropriate. As an alternative option, attach a document e.g. excerpt from the study report. Record the estimated half-life under 'Dissipation half-life of parent compound' in the Results section. Guidance on freetext template: - Concentration of OH radicals: e.g. '50000 molecules/cm ³ ' - Degradation rate constant: e.g. '18.3 x 10E-12 cm ³ /(molecule*sec)' - Temperature for which rate constant was calculated: e.g. '25 °C' - Computer programme: e.g. 'EPIWIN, part AOPWIN v.1.90. (2000)' or 'AOP based on SAR methods developed by Atkinson'	Text template	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.EstimationMethodIfUsed
Light source	Select light source used.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.LightSource
Light spectrum : wavelength in nm	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.LightSpectrumWavelengthInNm
Relative light intensity	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.RelativeLightIntensity

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Details on light source	Enter any relevant details on the light source. Use either of the two freetext templates as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DetailsOnLightSource
Details on test conditions	Briefly describe the experimental set-up and procedure used.	Text area	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions
Duration of test at given test condition	Indicate the test duration, temperature and initial test substance concentration at which test was conducted. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Duration
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Temp
Initial conc. measured	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.InitialConcMeasured
Duration of test at given test condition			

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Reference substance	Indicate whether the results with the reference substance(s) are valid.	Close list with remarks	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.ReferenceSubstance
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion
Preliminary study	Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.PreliminaryStudy
Test performance	Report on any unusual observations during test, deviations from test procedure or any other information affecting results.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.TestPerformance
Spectrum of substance	Select spectral parameter from picklist and enter value in the subsequent subfield. Any notes can be included in subfield 'Remarks on result'. Repeat field for each parameter cited in the study report. If the substance absorbs light at wavelengths >295 nm, give the wavelength (lambda value) of maximum absorption at wavelengths >295 nm and the maximum molar absorption (extinction) coefficient (epsilon value). If there is no absorption maximum at >295 nm, give the molar extinction coefficient at 295 nm. An alternative to the above is to attach a file that depicts graphically or in tabular form the complete UV/VIS absorption spectrum (include reference to respective Figure or Table No. in subfield 'Remarks on result').		ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.SpectrumOfSubstance
Parameter	Select parameter from drop-down list and enter the corresponding value or range with unit (unless dimensionless) in the related text field, together with any explanation if necessary, e.g. on the study group	Open list	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndD

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	<p>the result refers to. Explanations: AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration</p>		<p>discussion.SpectrumOfSubstance.Parameter</p>
Value	Enter numeric value.	Unit measure with Open List (Decimal)	<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.SpectrumOfSubstance.Value</p>
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' 	Open list with remarks (2000)	<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.SpectrumOfSubstance.RemarksOnResults</p>
Spectrum of substance			
% Degradation	Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.		<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation</p>
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.KeyResult</p>
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.Degr</p>

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St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.StDev
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.SamplingTime
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Quantum yield (for direct photolysis)	Give the reaction quantum yield of the test substance (values between 0 and 1).	Decimal	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.QuantumYield
Dissipation on half-life of parent compound	Provide the half-life / DT50 or range as appropriate. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationParentCompound
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationPa

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			rentCompound.KeyResult
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationParentCompound.DT50
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationParentCompound.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationParentCompound.RemarksOnResults
Dissipation half-life of parent compound			
Degradation rate constant	If provided, specify the rate constant for the reaction with OH radicals and/or ozone.		ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant.KeyResult
Reaction with	Select the type of molecule the substance reacts with from drop-down list, i.e. OH or ozone or select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant.ReactionWith

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Rate constant	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant.RateConstant
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant.RemarksOnResults
Degradation rate constant			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'. Not relevant for microorganisms	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'. Not relevant for microorganisms		ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.IdentityTrans

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			formation.ReferenceSubstance
Identity of transformation products			
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.ResultsReferenceSubstance
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ApplicantSummaryAndConclusion

9.3.2 Transport via air – Endpoint study record

Purpose:

Chemical active substance: If the trigger for volatilisation, $V_p = 10^{-5}$ Pa (plant) or 10^{-4} Pa (soil) at a temperature of 20 °C, is exceeded and (drift) mitigation measures are required, data from confined experiments may be reported.

Chemical product: Where relevant, laboratory, wind-tunnel or field experiments to determine PECS from deposition following volatilisation and mitigation measures shall be provided.

If needed, experiments to determine deposition following volatilisation may be provided.

The national competent authorities shall be consulted to decide whether this information is necessary.

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ENDPOINT_STUDY_RECORD.TransportViaAir v1.2 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.TransportViaAir.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.TransportViaAir.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.TransportViaAir.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.ApplicantSummaryAndConclusion

Links to support material:

Pesticides in Air: Considerations for Exposure Assessment”. Report of the FOCUS Working Group on Pesticides in Air (SANCO/10553/2006 Rev 2 June 2008)

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9.4 Estimation of concentrations for other routes of exposure – Flexible summary

<p>Purpose Suitable estimations (calculations) of predicted environmental concentration, of active substance and metabolites, breakdown and reaction products shall be submitted unless the applicant shows that contamination will not occur in case of exposure by other routes, such as: deposition of dust containing plant protection products by drift during sowing, indirect exposure of surface water via a sewage treatment plant (STP) after application of a plant protection product in storage rooms, and amenity use. PEC estimations shall relate to the maximum number and highest rates of application, at the shortest interval, for which authorisation is sought, and be relevant to the relevant environmental compartments.</p> <p>This document can also be used to report predicted environmental concentrations for microorganisms and its metabolites.</p>
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FLEXIBLE_SUMMARY.EstConcOtherRoutes – v.1.0 (Final) [August 2020]			
Name	Instructions	Data type	Field path
Administrative data		Header 1	FLEXIBLE_SUMMARY.EstConcOtherRoutes.AdministrativeDataSummary
Link to relevant summary record(s)	Provide the link to the most relevant endpoint summaries used to predict environmental concentrations	Header 1	FLEXIBLE_SUMMARY.EstConcOtherRoutes.RelevantSummaries
Summaries used as input parameters		Endpoint reference list	FLEXIBLE_SUMMARY.EstConcOtherRoutes.RelevantSummaries.InputSummaries
Description of key information	Indicate the route of exposure and conclude on the predicted environmental concentration for the route/s	Header 1	FLEXIBLE_SUMMARY.EstConcOtherRoutes.KeyInformation
		Rich text area	FLEXIBLE_SUMMARY.EstConcOtherRoutes.KeyInformation.field357
PEC from other routes of exposure		Header 1	FLEXIBLE_SUMMARY.EstConcOtherRoutes.PECOtherRoutes
PEC other routes			FLEXIBLE_SUMMARY.EstConcOtherRoutes.PECOtherRoutes.PECOtherRoutesRep
Use description	Select the GAP document/s for the use	Endpoint reference list	FLEXIBLE_SUMMARY.EstConcOtherRoutes.PECOtherRoutes.PECOtherRoutesRep.UseDescription

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Parent / metabolite	Indicate whether the predicted concentration related to the parent or the metabolite	Closed list	FLEXIBLE_SUMMARY.EstConcOtherRoutes.PECOtherRoutes.PECOtherRoutesRep.ParentMetabolite
Substance	Select the substance for the predicted concentration	Entity reference field	FLEXIBLE_SUMMARY.EstConcOtherRoutes.PECOtherRoutes.PECOtherRoutesRep.Substance
Route of exposure	Describe the route of exposure	Multi-line text	FLEXIBLE_SUMMARY.EstConcOtherRoutes.PECOtherRoutes.PECOtherRoutesRep.RouteOfExposure
Method of calculation	Report the model or method of calculation	Text area	FLEXIBLE_SUMMARY.EstConcOtherRoutes.PECOtherRoutes.PECOtherRoutesRep.MethodOfCalculation
PEC	Report the value of the predicted concentration	Unit measure with Open List (Decimal)	FLEXIBLE_SUMMARY.EstConcOtherRoutes.PECOtherRoutes.PECOtherRoutesRep.PEC
PEC other routes			
Additional information	Discussion (Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.EstConcOtherRoutes.Discussion

10 Ecotoxicological studies - Flexible record

Purpose

This document can be used to provide an overall assessment of the ecotoxicological effects of the active substance/plant protection product on the different groups of non-target organisms (NTOs) based on the available studies.

For each group of NTOs (birds and other terrestrial vertebrates, aquatic organisms, bees and other non-target arthropods, soil macro, terrestrial non-target higher plants, and micro-organisms and organisms involved in biological sewage treatment), the outcome of the risk assessment according to the agreed guidelines should be summarised.

FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides v.1.1

Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.AdministrativeDataSummary

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Ecotoxicological risk assessment of pesticides	This document can be used to provide an overall assessment of the toxicological effects on non-target organisms based on the studies provided in this section.	Header 1	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides
Risk assessment to birds		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentBirds
	Provide a summary of the risk assessment to birds. A table with the toxicity:exposure ratios following the EFSA birds and mammals guidance (EFSA, 2009) can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentBirds.field9187
Risk assessment to wild mammals		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentWildMammals
	Provide a summary of the risk assessment to wild mammals. A table with the toxicity:exposure ratios following the EFSA birds and mammals guidance (EFSA, 2009) can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentWildMammals.field8618
Risk assessment to other terrestrial vertebrates		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentOtherTerrestrialVertebrates
	Provide a summary of the risk assessment to other non-target vertebrates other than birds and mammals.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentOtherTerrestrialVertebrates.field593
Risk assessment to aquatic organisms		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentAquaticOrganisms
	Provide a summary of the risk assessment to aquatic organisms. A table with the regulatory acceptable concentrations for the relevant groups of aquatic organisms following the	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessment

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	EFSA aquatic guidance document (EFSA, 2013) can be included.		tAquaticOrganisms.field4291
Risk assessment to bees		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentBees
	Provide a summary of the risk assessment to bees. A table with the hazard quotients and exposure: toxicity ratios for the relevant routes of exposure can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentBees.field9185
Risk assessment to non-target arthropods other than bees		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentNonBees
	Provide a summary of the risk assessment to non-target arthropods other than bees. A table with the hazard quotients for the species tested and for the in-field and off-field scenarios following ESCORT 2 can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentNonBees.field5875
Risk assessment to non-target soil meso- and macrofauna		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSoilMesoMacrofauna
	Provide a summary of the risk assessment to soil organisms. A table with the toxicity: exposure ratios for the relevant groups of soil organisms (earthworms, collembolans, predatory mites) following the guidance document on terrestrial ecotoxicology SANCO/10329/2002 can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSoilMesoMacrofauna.field9216
Risk assessment to soil nitrogen transformation		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSoilTransformation
	Provide a summary of the risk assessment to soil nitrogen transformation.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessment

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			Pesticides.RiskAssessmentSoilTransformation.field9651
Risk assessment to terrestrial non-target higher plants		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentHigherPlants
	Provide a summary of the probabilistic/deterministic risk assessment to terrestrial non-target higher plants. A table with the toxicity: exposure ratios following the guidance document on terrestrial ecotoxicology SANCO/10329/2002 can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentHigherPlants.field4576
Risk assessment to biological methods for sewage treatment		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSewageTreatmentMethods
	Provide a summary of the risk assessment to microorganism involved in biological sewage treatment.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSewageTreatmentMethods.field6508
Risk assessment to other terrestrial organisms (flora and fauna)		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentToOtherTerrestrialOrganismsFloraAndFauna
		Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentToOtherTerrestrialOrganismsFloraAndFauna.field2441
Additional information for the	Discussion (Header 1) – common block A document as attachment pdf/doc can be provided where the risk assessment for the	Header 1	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.AdditionalInformation

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ecotoxicological risk assessment of pesticides	different taxa is conducted according to the agreed guidelines and for addressing the EU pesticides data requirements. The original version of the document should be provided if it differs from the publication version.		
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10.1 Effects on birds and other terrestrial vertebrates

10.1.1 Effects on birds (acute, short-term dietary, sub-chronic and reproductive) - Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, including:</p> <ul style="list-style-type: none"> - Category (e.g. insectivorous bird) and species, - Time-scale, - Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects).

ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa
Short-term toxicity to birds			ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.ShortTermToxicity
Study name / type	Select the study for which the endpoint was derived.	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.ShortTermToxicity.Link
Test organisms	Select the organism(s) for which the endpoint was derived.	Multi select open	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.S

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(species)		list with remarks	hortTermToxicity.Tes tOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMAR Y.ToxicityBirds_EU_P PP.KeyValueForCsa.S hortTermToxicity.Par entMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity referen ce field	ENDPOINT_SUMMAR Y.ToxicityBirds_EU_P PP.KeyValueForCsa.S hortTermToxicity.Sub stance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect." In the long-term study: Select 'not specified' if the effect concentration type is not known.	Multi select open list with remarks	ENDPOINT_SUMMAR Y.ToxicityBirds_EU_P PP.KeyValueForCsa.S hortTermToxicity.Bas isForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed. If it is a corrected value, please indicate why.	Closed list	ENDPOINT_SUMMAR Y.ToxicityBirds_EU_P PP.KeyValueForCsa.S hortTermToxicity.Dos eDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In (mg/kg bw per day) . For micro-organisms, average achieved dose in colony forming units (cfu) also must be reported.	Range with closed list (Decim al)	ENDPOINT_SUMMAR Y.ToxicityBirds_EU_P PP.KeyValueForCsa.S hortTermToxicity.Eff ectConcentration
Short-term toxicity to birds			
Long-term toxicity to birds			ENDPOINT_SUMMAR Y.ToxicityBirds_EU_P PP.KeyValueForCsa.L ongTermToxicity
Study name / type	Select the study for which the endpoint was derived.	Endpoin t referen ce field	ENDPOINT_SUMMAR Y.ToxicityBirds_EU_P PP.KeyValueForCsa.L ongTermToxicity.Link
Test organis	Select the organism(s) for which the endpoint was derived.	Multi select	ENDPOINT_SUMMAR Y.ToxicityBirds_EU_P

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ms (species)		open list with remarks	PP.KeyValueForCsa.LongTermToxicity.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect."	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed. If it is a corrected value, please indicate why.	Open list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In (mg/kg bw per day). For micro-organisms, average achieved dose in colony forming units (cfu) must be reported.	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.EffectConcentration
Long-term toxicity to birds			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa). Information concerning the residue decline in potential food items of birds can be described here. Make reference to endpoint studies used in this analysis	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.HigherTierTesting.field1350

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Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.Discussion
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10.1.1 Effects on birds (acute, short-term dietary, sub-chronic and reproductive) - Endpoint study record

Purpose

Information on toxicity, infectiveness and pathogenicity to birds must be reported.

A study shall be provided establishing the acute oral toxicity (LD₅₀) of the active substance. The study shall provide, where possible, LD₅₀ values. The lethal threshold dose, time courses of response and recovery, the LD₁₀ and LD₂₀ shall be reported together with the no observed effect level (NOEL) and gross pathological findings. Where LD₁₀ and LD₂₀ cannot be estimated, an explanation shall be provided. Study design shall be optimised for the achievement of an accurate LD₅₀.

A study shall be provided establishing the short-term dietary toxicity. LC₅₀ values, lowest lethal concentration (LLC), where possible, no observed effect concentration (NOEC) values, time courses of response and recovery and pathological findings shall be reported in such study. LC₅₀ and NOEC values shall be converted to daily dietary dose (LD₅₀) expressed in mg substance/kg bw/day and NOEL expressed in mg substance/kg bw/day.

A study shall be provided establishing the sub-chronic and reproductive toxicity of the substance to birds. The EC₁₀ and EC₂₀ shall be reported. Where they cannot be estimated, an explanation shall be provided together with the NOEC expressed in mg substance/kg bw/day.

ENDPOINT_STUDY_RECORD.ToxicityToBirds – v.7.4 (Final) [September 2020]			
Name	Instructions	Data Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToBirds.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline No 223: Avian acute oral toxicity study	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods

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	<p>OECD Test Guideline No 223: Avian acute oral toxicity study (updated version of July 2016) US EPA OCSPP 850.2100: Avian oral toxicity test OECD Test Guideline 205: Avian Dietary Toxicity Test US EPA OCSPP 850.2200: Avian dietary toxicity test. OECD Test Guideline 206: Avian Reproduction Test US EPA OCSPP 850.2300: Avian Reproduction Test OPPTS 885.4050 Avian Oral, Tier I OPPTS 885.4600 Avian Chronic Pathogenicity and Reproduction Test, Tier III</p>		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Dose method	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.DoseMethod
Analytical monitoring	Indicate whether test substance was monitored in the test medium. If yes, specify in field 'Details on	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.AnalyticalMonitoring

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	preparation and monitoring of diet'.		
Vehicle	Indicate whether a vehicle was used, e.g. to disperse/solubilise or facilitate mixing of test substance with feed.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.Vehicle
Details on preparation and analysis of diet	Indicate whether a vehicle was used, e.g. to disperse/solubilise or facilitate mixing of test substance with feed. Indicate details about diet preparation and homogeneity analysis of test material. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. In the case of OECD or similarly acknowledged guideline only items may be covered where deviations apply or where parameters are left open in the guideline, provided the respective regulatory programme allows so.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.DetailsOnPreparationAndAnalysisOfDiet
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestOrganisms
Test organisms (species)	Select the species from the picklist. If not available, select 'other' and enter the species name of the test organism.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Details on test organisms	Enter any details that could be relevant for evaluating this study summary. Use free-text	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.T

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	template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.		estOrganisms.DetailsOnTestOrganisms
Study design		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.LimitTest
Total exposure duration (if not single dose)	Select from drop-down list.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.TotalExposureDuration
Remarks	Enter any remarks related to the total exposure duration.	Text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.Remarks
Post exposure observation period	Indicate the post-observation period (with unit) during which 'clean' feed was administered.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.PostExposureObservationPeriod
No. of animals per sex per dose and/or stage	Indicate the post-observation period (with unit) during which 'clean' feed was administered. Indicate number of animals used per dose group and/or stage. State if different numbers were used and reason why.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.ControlAnimals

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<p>Nominal and measured doses / concentrations</p>	<p>List nominal and, if available, measured dose levels or test concentrations (with unit). Indicate if nominal or measured for bolus dose, etc. Provide range, median, mean, SD as applicable. As appropriate tabulate nominal vs. measured concentrations and refer to Table no.</p> <p>For micro-organisms, average achieved dose in colony forming units (cfu) also must be reported.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.NominalAndMeasuredDosesConcentrations</p>
<p>Details on test conditions</p>	<p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions</p>
<p>Examinations</p>		<p>Header 2</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Examinations</p>
<p>Details on examinations and observations</p>	<p>Indicate the time schedule and further details for all examinations and observations performed (use separate free-text field for reproductive parameters, if applicable). Also indicate the dose groups that were</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.ExaminationsAndObservations</p>

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	<p>examined if not all. When tabulating parameters examined, refer to respective table no. Use free-text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
Details on reproductive parameters	<p>For avian reproduction toxicity test, indicate the reproductive parameters examined. Use free-text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Examinations.DetailsOnReproductiveParameters
Reference substance (positive control)	<p>Indicate if a positive control was tested, i.e. a reference substance with known toxicity. If yes, include the identity of the substance(s) and the concentrations in the supplementary remarks field.</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Examinations.ReferenceSubstancePositiveControl
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p>	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

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Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion
Effect levels	Report the LC50, LD50, NOEC or LOEC for appropriate parental and reproductive parameters depending on the study type. Copy this field block for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.KeyResult
Duration (if not single dose)	Enter numeric value (not relevant for bolus dose) and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.EffectLevel
Conc. / dose based on	Indicate whether the concentration is based on the test material (test mat.), active	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.Eff

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	ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.		ectLevels.ConcDoseBas edOn
Basis for effect	Select effect parameter such as mortality, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field, e.g. 'related to number of eggs or young surviving'.	Open list with remarks	ENDPOINT_STUDY_RE CORD.ToxicityToBirds.R esultsAndDiscussion.Eff ectLevels.BasisForEffect
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and	Open list with remarks (2000)	ENDPOINT_STUDY_RE CORD.ToxicityToBirds.R esultsAndDiscussion.Eff ectLevels.RemarksOnRe sults

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	entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'		
Effect levels			
Repellency factors (if applicable)	If repellency was investigated, describe the repellency results including all repellency factors (RF) given in the study report, i.e. either for each bird (choice test) or for per test group (no-choice test). As appropriate include or attach a table.	Multi-line text	ENDPOINT_STUDY_RESULT_TOXICITY_TO_BIRDS_RESULTS_AND_DISCUSSION_REPELLENCY_FACTORS
Mortality and sub-lethal effects	Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RESULT_TOXICITY_TO_BIRDS_RESULTS_AND_DISCUSSION_MORTALITY_AND_SUBLETHAL_EFFECTS

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<p>Effects on reproduction</p>	<p>For avian reproduction toxicity test, include data on reproduction during pre-treatment and treatment periods depending on the requirements of the test guideline used. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectsOnReproduction</p>
<p>Results with reference substance (positive control)</p>	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.ResultsWithReferenceSubstance</p>
<p>Further details on results</p>	<p>For microbial organisms, information on infectiveness and</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.FurtherDetailsOnResults</p>

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	pathogenicity to birds must be reported.		
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.ReportedStatisticsAndErrorEstimates
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ApplicantSummaryAndConclusion

Links to support materials

OECD series of testing and assessment Number 54. "Current approaches in the statistical analysis of ecotoxicity data: a guidance to application"

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2006\)18&docLanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2006)18&docLanguage=en)

EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438.

10.1.2 Effects on terrestrial vertebrates other than birds – Endpoint summary

Purpose:

Summarise the most relevant information from the available relevant acute and long-term study(-ies) derived from the mammalian toxicological assessment.

This information could include, for instance:

- The test guideline used;
- The test organism tested;
- The exposure duration;
- The results obtained.

ENDPOINT_SUMMARY.TerrestrialToxicity v5.0 (Final) [July 2020]

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Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.TerrestrialToxicity.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.TerrestrialToxicity.Discussion

Links to support material:

EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. <https://doi.org/10.2903/j.efsa.2009.1438>

10.1.2.2 Higher tier data on mammals – Endpoint summary

Purpose:

Chemicals active substance: Conclude on the available and relevant data, including data from the open literature for the active substance of concern, regarding the potential effects to birds, mammals, reptiles and amphibians.

Chemicals product: Where it cannot be predicted from the active substance data and, if relevant, conclude on the risk to amphibians and reptiles from plant protection products considering the submitted endpoint studies

ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP v1.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa
Short-term toxicity to other above-ground organisms (wild mammals)			ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther
Study name / type		Endpoint reference field	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.Link
Test organisms (species)	Select the organism(s) for which the endpoint was derived. Select 'not specified' if the	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.TestOrganismsSpecies

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	effect concentration type is not known.		
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.ParentMetabolite
Substance	Select the test substance.	Entity reference field	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed.	Closed list	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable.	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.EffectConcentration
Short-term toxicity to other above-ground organisms (wild mammals)			
Long-term toxicity to other above-ground			ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther

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organisms (wild mammals)			
Study name / type		Endpoint reference field	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.Link
Test organisms (species)	Select the organism(s) for which the endpoint was derived.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.TestOrganismsSpecies
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.ParentMetabolite
Substance	Select the test substance.	Entity reference field	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.Substance
Basis for effect	Select the type of effect for the endpoint setting (e.g. mortality, reproduction, behaviour, etc.).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed.	Open list	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable.	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.EffectConcentration
Long-term toxicity to other above-ground			

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organisms (wild mammals)			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.Discussion

Links to support material

EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438.

OECD series of testing and assessment Number 54. "Current approaches in the statistical analysis of ecotoxicity data: a guidance to application"

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)

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10.1.2.2 Higher tier data on mammals – Endpoint summary

Purpose:

Microorganisms: Any available information on the effects on non-target organisms within the area to which the micro-organism may spread shall be given. The occurrence of non-target organisms being either closely related to the target species or being especially exposed shall be indicated.

Any experience of the toxic effect of the active substance or its metabolic products on humans or animals, of whether the organism is capable of colonising or invading humans or animals (including immunosuppressed individuals) and whether it is pathogenic shall be stated. Any experience of whether the active substance or its products may irritate skin, eyes or respiratory organs of humans or animals and whether it is allergenic in contact with skin or when inhaled shall be stated.

Chemicals: Higher tier studies on mammals shall be conducted where the first tiers of the risk assessment do not demonstrate that risk is acceptable

Where it cannot be predicted from the active substance data and, if relevant, the risk to amphibians and reptiles from plant protection products shall be addressed. The type and conditions of the studies to be provided shall be discussed with the national competent authorities.

ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms v.6.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.SamplingAndAnalysis

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Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.StudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.ApplicantSummaryAndConclusion

10.2 Effects on aquatic organisms – Flexible summary

<p>Purpose: Regulatory acceptable concentration (RAC) values estimated dividing the derived endpoints by the corresponding assessment factor should be reported for the relevant groups of aquatic organisms (fish, aquatic invertebrates, algae, sediment-dwellers, macrophytes) following the EFSA aquatic guidance document (EFSA, 2013).</p>

FLEXIBLE_SUMMARY.AquaticToxicityRacReporting v1.1 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.AdministrativeDataSummary
RAC values	Report the RAC values according to the EFSA, 2013.		FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues
Parent / metabolite	Specify whether the RAC refers to the parent or to a metabolite.	Closed list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.ParentMetabolite

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Substance	Specify the name of the active substance or metabolite to which the information refers to.	Entity reference field	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.Substance
Test organisms	Select the relevant aquatic organism group to which the information refers.	Multi select open list with remarks	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.TestOrganisms
Time scale	Select the time scale for the risk assessment.	Closed list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.TimeScale
Tier	Select the tier for the risk assessment.	Closed list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.Tier
Assessment factor	Select the assessment factor for the risk assessment.	Multi select open list with remarks	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.AssessmentFactor
Type of RAC value	Select the type of RAC derived.	Closed list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.RacValueType
RAC value	Include the RAC value and the pertinent units.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.RacValue
RAC values			
Additional information	Provide additional information related to the RAC derivation that was not possible to capture in previous fields.	Header 1	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion
		Rich text area	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.Discussion
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.		FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.AttachedBackgroundMaterial
Attached document	Provide any additional documents relevant for the submission.	Single file attachment	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.AttachedDocument

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			chedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	If required, an electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. These attachments should be sanitised if needed.	Attachments list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.AttachedSanitisedDocsForPublication

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Links to support material:

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. <https://doi.org/10.2903/j.efsa.2013.3290>

10.2.1 Acute toxicity to fish- Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details:

- Group: Specify Fish species;
- Time scale;
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects).

ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP – v.1.3 (Final) [October 2020]

Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment	Section for reporting of tier 1 studies.	Header 1	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa
Short-term toxicity to freshwater fish			ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwaterFish
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwaterFish.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.S

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			hortTermToxicityFresh waterFish.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFresh waterFish.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFresh waterFish.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (EC50, LC50 or NOEC).	Closed list	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFresh waterFish.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range, use both numeric fields together with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFresh waterFish.EffectConcentration
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid	Open list	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFresh waterFish.NominalMeasured

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	equivalent or estimated. Select 'not specified' if not known.		
Short-term toxicity to freshwater fish			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.Discussion

Links to support materials

OECD. Series on testing and assessment No 126. Short guidance on the threshold approach for acute fish toxicity. ENV/JM/MONO(2010)17

<https://ntp.niehs.nih.gov/iccvam/suppdocs/feddocs/oecd/oecd-gd126.pdf>

10.2.1 Acute toxicity to fish - Endpoint study record

Purpose

A study shall be provided on the acute toxicity to fish (LC₅₀) and details of observed effects. Information on toxicity, infectiveness and pathogenicity to fish must be reported

ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish – v. 6.5 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.Administrative Data
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.DataSource
Reference	Literature reference	Literature reference	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.LiteratureReference

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		nce list	yToFish.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 203: Fish, Acute Toxicity Test EPA OPPTS 885.4200 - Freshwater Fish Testing, Tier I (February 1996)	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block In the “nominal and measured concentrations” field, the average achieved dose in cfu must be reported.	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDisc

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			ussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	For acute fish test, select effect parameter such as mortality or visible abnormalities related to appearance and behaviour. As appropriate include further details in	Open list with	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDisc

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	<p>the supplementary remarks field.</p> <p>For fish embryo test, select indicators of mortality (or lethality): (i) coagulation of fertilised eggs, (ii) lack of somite formation, (iii) lack of detachment of the tail-bud from the yolk sac, and (iv) lack of heartbeat. As appropriate include further details in the supplementary remarks field.</p>	remarks	ussion.EffectConcentrations.BasisForEffect
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	Information on toxicity, infectiveness and pathogenicity to fish must be reported.	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.ResultsDetails
Results with reference substance (positive control)	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.Statistics

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Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Sublethal observations / clinical signs	<p>In this field, you can enter any other remarks on results or observations e.g. sub lethal effects recorded during the study. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.</p> <p>Optionally include clinical signs, using predefined (or other) table as proposed in TG 203, Annex 4.</p> <p>Percentages of test animals that showed symptomology.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	Rich text area	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.SublethalObservationsClinicalSigns
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ApplicantSummaryAndConclusion

10.2.2 Long-term and chronic toxicity to fish - Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details:

- Group: Specify fish species
- Time scale
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)

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ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP – v.1.4 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment	Section specific for reporting of tier 1 studies.	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment
Long-term toxicity to freshwater fish			ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed. If it is a corrected value, please indicate why.	Closed list	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAs

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			essment.LongTermToxFresh waterFish.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable.	Range with closed list (Decimal)	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFresh waterFish.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Open list	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFresh waterFish.NominalMeasured
Long-term toxicity to freshwater fish			
EC10, LC10 or NOEC for marine water fish	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	Range with closed list (Decimal)	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.EcTenLcTenNoecMarineWaterFish
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.Discussion

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10.2.2 Long-term and chronic toxicity to fish - Endpoint study record

Purpose

A long-term or chronic toxicity study on fish shall be provided for all active substances where exposure of surface water is likely and the substance is deemed to be stable in water, that is to say there is less than 90 % loss of the original substance over 24 hours via hydrolysis (see point 7.2.1.1). A fish early life stage study shall be provided in these circumstances. However, if a fish full life cycle study is provided an early life stage study shall not be required. Information on toxicity, infectiveness and pathogenicity to fish must be reported.

ENDPOINT_STUDY_RECORD.LongTermToxToFish – v.6.5 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxToFish.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxToFish.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.LongTermToxToFish.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OPPTS 885.4700 Fish Life Cycle Studies, Tier III OECD Test Guideline 210: Fish, Early-Life Stage Toxicity Test US EPA protocol OCSP 850.1500 Fish life cycle toxicity Are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods

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			ds.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods.TestOrganisms
Test organisms (species)	Select the name of the species. If not available, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Details on test organisms	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block Nominal and measured concentrations: Actual achieved dose in colony forming must be reported.	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxToFish.ResultsAndDiscussion

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	Details on results: Information on toxicity, infectiveness and pathogenicity to fish must be reported Isolation, identification, and enumeration of microorganisms responsible for any observed pathogenic effects.		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxToFish.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxToFish.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxToFish.ApplicantSummaryAndConclusion

10.2.3 Acute toxicity to aquatic invertebrates - Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g.:</p> <ul style="list-style-type: none"> - Group: Specify Invertebrate species; - Time scale; - Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects) 			
ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.AdministrativeDataSummary

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Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa
Short-term toxicity to aquatic invertebrates			ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.TestOrganismsSpecies
Parent / metabolite	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Closed list	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.ParentMetabolite
Substance	Indicate whether the endpoint is for the active substance or a metabolite	Entity reference field	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (EC50 or LC50).	Closed list	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together	Half-bounded with closed list	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates

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	with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	(Decimal)	brates.EffectConcentration
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Open list	ENDPOINT_SUMMARY.ShortTermToxicityAquaInverte_EU_PPP.KeyValueCsa.ShortTermTox AquaInvertebrates.NominalMeasured
Short-term toxicity to aquatic invertebrates			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ShortTermToxicityAquaInverte_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ShortTermToxicityAquaInverte_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ShortTermToxicityAquaInverte_EU_PPP.Discussion

Links to support material:

Guidance Document on Tiered Risk Assessment for Plant Protection products for Aquatic Organisms in Edge-of-field Surface Waters in the Context of Regulation (EC) No 1107/2009 (SANTE-2015-00080, 15 January 2015) https://www.efsa.europa.eu/en/efsajournal/pub/3290_10.2903/j.efsa.2013.3290

10.2.3 Acute toxicity to aquatic invertebrates - Endpoint study record

Purpose

The acute toxicity shall be determined for a *Daphnia* species (preferably *Daphnia magna*). For active substances with an insecticidal mode of action or which show insecticidal activity a second species shall be tested, for example Chironomid larvae or Mysid shrimps (*Americamysis bahia*). A test shall be provided on the 24- and 48-hour acute toxicity of the active substance to *Daphnia magna*, expressed as the median effective concentration (EC₅₀) for immobilisation, and where possible, the highest concentration causing no immobilisation.

Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.

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ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv – v.7.4 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.Data Source
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.Data Source.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 202: <i>Daphnia sp.</i> Acute Immobilisation Test US EPA OCSPP 850.1035 Mysid Acute Toxicity Test OECD Test Guideline 235: <i>Chironomus sp.</i> , Acute Immobilisation Test OPPTS 885.4240 Freshwater Aquatic Invertebrate Testing, Tier I	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.Test Materials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.Test Materials.TestMaterial Information
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ShortTermTo

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			xicityToAquaInv.Mate rialsAndMethods.Stud yDesign
Test condition s	Test conditions block Nominal and measured concentrations: Actual achieved dose in colony forming units must be reported.	Heade r 2	ENDPOINT_STUDY_R ECORD.ShortTermTo xicityToAquaInv.Mate rialsAndMethods.Test Conditions
Any other informati on on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block A detailed description of the steps taken to determine microorganism dissemination, replication, or survival in the test animal tissues, organs, or fluids.	Heade r 2	ENDPOINT_STUDY_R ECORD.ShortTermTo xicityToAquaInv.Mate rialsAndMethods.Any OtherInformationOn MaterialsAndMethods InclTables
Results and discussio n	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Heade r 1	ENDPOINT_STUDY_R ECORD.ShortTermTo xicityToAquaInv.Resu ltsAndDiscussion
Effect concentr ations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_R ECORD.ShortTermTo xicityToAquaInv.Resu ltsAndDiscussion.Effe ctConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_R ECORD.ShortTermTo xicityToAquaInv.Resu ltsAndDiscussion.Effe ctConcentrations.Key Result
Duration	Enter numeric value.	Unit meas ure with Close d List (Deci mal)	ENDPOINT_STUDY_R ECORD.ShortTermTo xicityToAquaInv.Resu ltsAndDiscussion.Effe ctConcentrations.Dur ation
Dose descripto r	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remar ks	ENDPOINT_STUDY_R ECORD.ShortTermTo xicityToAquaInv.Resu ltsAndDiscussion.Effe ctConcentrations.End point

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Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Close list	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults

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Effect concentrations			
Details on results	<p>For micro-organisms, information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.</p> <p>Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>As appropriate also attach a figure with growth curves in field 'Attached background material'. Note: Specific tables may be required.</p>	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.ResultsDetails
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	<p>Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ApplicantSummaryAndConclusion
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10.2.4 Long-term and chronic toxicity to aquatic invertebrates- Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g.:</p> <ul style="list-style-type: none"> - Group: Specify Invertebrate species; - Time scale; - Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects).

ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa
Long-term toxicity to aquatic invertebrates			ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates
Study name / type	Select the study/ies from which the endpoint was derived	Endpoint reference field	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.Link
Animal group	Indicate the taxa for which the endpoint below was derived according to the classification given in the EU data	Multi-line text	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.AnimalGroup

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	requirements (e.g. earthworms, collembola, etc).		
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.Substance
Basis for effect	Select the type of effect for endpoint setting. Select 'not specified' if the effect concentration type is not known.	Multi select open list with remarks	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (e.g. EC10, LC10, NOEC).	Closed list	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range, use both numeric fields together with the appropriate qualifier(s),	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.EffectConcentration

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	if applicable. In mg or µg a.s./L		
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Open list	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.NominalMeasured
Long-term toxicity to aquatic invertebrates			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.Discussion

Links to support material

Guidance Document on Tiered Risk Assessment for Plant Protection products for Aquatic Organisms in Edge-of-field Surface Waters in the Context of Regulation (EC) No 1107/2009 (SANTE-2015-00080, 15 January 2015) https://www.efsa.europa.eu/en/efsajournal/pub/3290_10.2903/j.efsa.2013.3290

10.2.4 Long-term and chronic toxicity to aquatic invertebrates - Endpoint study record

Purpose

Chemicals: A long-term or chronic toxicity study on aquatic invertebrates shall be provided for all active substances where exposure of surface water is likely and the substance is deemed to be stable in water, that is to say there is less than 90 % loss of the original substance over 24 hours via hydrolysis.

Microorganisms: Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.

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ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv – v.6.4 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 211: <i>Daphnia magna</i> Reproduction Test US EPA OCSPP 850.1350 Mysid Chronic Toxicity Test OECD Test Guideline 242: Potamopyrgus antipodarum Reproduction Test OECD Test Guideline 243: Lymnaea stagnalis Reproduction Test OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment OECD Test Guideline 233: Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment OECD Test Guideline 225: Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment OPPTS 885.4650 Aquatic Invertebrate Range Testing, Tier III	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.TestMaterials

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Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block Nominal and measured concentrations: For microorganisms :Average achieved dose in colony forming units (cfu) also must be reported.	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsIncTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.KeyResult

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Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived;	Open list with	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.Results

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	<p>- giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or</p> <p>- entering any additional information on the effect level by selecting 'other:'</p> <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>	remarks (2000)	sAndDiscussion.Effect Concentrations.RemarksOnResults
Effect concentrations			
Details on results	<p>For microorganisms: Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.</p> <p>Briefly summarize relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.</p> <p>Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Text template	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.ResultsDetails
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	<p>Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.Statistics

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Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.OverallRemarksAttachments
Attached background material			
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ApplicantSummaryAndConclusion

10.2.5 Effects on algae growth - Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details e.g</p> <p>Chemicals: Growth rate, Biomass, Yield EC50/NOEC. Microorganisms: Effects on algal growth, growth rate and capacity to recover</p>
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ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Data type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.AdministrativeDataSummary
Key value for chemical safety		Header 1	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa

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assessment			
Toxicity to algae			ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae
Study name / type	Select the study from which the endpoint was derived.	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.Link
Test organisms (species)	Select the species from the picklist. If not available, select 'other:' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.Substance
Basis for effect	Select the type of effect for the endpoint setting.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (e.g. EbC10, ErC20, NOEC).	Closed list	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.EffectConcentration
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average =	Open list	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValue

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	TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.		eCsa.ToxAlgae.NominalMeasured
Toxicity to algae			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.Discussion

Links to support material:

Guidance Document on Tiered Risk Assessment for Plant Protection products for Aquatic Organisms in Edge-of-field Surface Waters in the Context of Regulation (EC) No 1107/2009 (SANTE-2015-00080, 15 January 2015)

https://www.efsa.europa.eu/en/efsajournal/pub/3290_10.2903/j.efsa.2013.3290

10.2.5 Effects on algae growth - Endpoint study record

Purpose

Information on effects on algal growth, growth rate and capacity to recover must be reported.

A test shall be provided establishing EC10, EC20, EC50 for green algae and corresponding NOEC values for algal growth rate and yield, based on measurements of biomass or surrogate measurement variables.

ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae – v.7.6 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToA

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			quaticAlgae.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 201: Algae growth inhibition test is relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block Nominal and measured concentrations: the average achieved dose and relevant units must be reported.	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

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Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectC

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	fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.		oncentrations.ConcB asedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	Information on effects on algal growth, growth rate and capacity to recover must be reported. Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). As appropriate also attach a figure with growth curves in	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.ResultsDetails

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	field 'Attached background material'. Note: Specific tables may be required.		
Results with reference substance (positive control)	Results with reference substance (positive control) - If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide EC50 data and other relevant information. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship. In addition, report the growth curves and the graphical presentation of the concentration-effect relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ApplicantSummaryAndConclusion

10.2.6 Effects on aquatic macrophytes - Endpoint summary

Purpose	Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g., species, growth rate, Biomass, Yield ECx/NOEC.
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ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Data type	Field path

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Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.AdministrativeDataSummary
Description of key information	Enter a short description of the most relevant endpoint data. The short description could include for example: -the test guideline used, -the test organism, -the exposure duration, -the contextual information of the origin of the value, -qualitative characterisation of some properties. The results (i.e. biological findings) should be presented in tabular format.	Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyInformation
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa
Toxicity to aquatic plants			ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants
Study name / type	Select the study from which the endpoint was derived	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.Link
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species)	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.Substance
Basis for effect	Select the type of effect for the endpoint setting.	Multi select open list	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.Tox

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		with remarks	AquaticPlants.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (e.g NOEC, EC20).	Closed list	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxicityPlants.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. In mg or µg a.s./L	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxicityPlants.EffectConcentration
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Open list	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxicityPlants.NominalMeasured
Toxicity to aquatic plants			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies).	Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.Discussion

Links to support material

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

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10.2.6 Effects on aquatic macrophytes - Endpoint study record

Purpose

Information on effects on plants other than algae must be reported.

A test shall be provided establishing EC10, EC20, EC50 and corresponding NOEC values for *Lemna* species growth rate and yield, based on measurements of number of fronds and at least one additional measurement variable (dry weight, fresh weight or frond area).

For other species of aquatic macrophytes, a test shall provide sufficient information to evaluate impact on aquatic plants and provide EC10, EC20, EC50 and corresponding NOEC values based on measurement of appropriate biomass parameters.

ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant – v.7.7 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.Data Source
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.Data Source.Reference
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 221: <i>Lemna sp.</i> Growth Inhibition Test ASTM E1913-04: Standard Guide for Conducting Static, Axenic, 14-Day Phytotoxicity Tests in Test Tubes with the Submersed Aquatic Macrophyte, <i>Myriophyllum sibiricum Komarov</i> OECD Test Guideline 238: Sediment-Free <i>Myriophyllum Spicatum</i> Toxicity Test OECD Test Guideline 239: Water-Sediment <i>Myriophyllum Spicatum</i> Toxicity Test OPPTS 885.4300 Nontarget Plant Studies, Tier I	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.Mate

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			rialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.KeyResult

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Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Actual achieved dose in relevant units must be reported. Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameters such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.BasisForEffect

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		with remarks	fectConcentrations.BasisForEffectMulti
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	<p>Any abnormal adverse or beneficial effects in treatment and/or control groups, including dates and times the effects were observed, should be reported.</p> <p>Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.</p> <p>Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.ResultsDetails
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information.</p> <p>Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and	<p>Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.Resu

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error estimates	probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.		ItsAndDiscussion.St atistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ApplicantSummaryAndConclusion

10.2.7 Further testing on aquatic organisms – Endpoint summary

<p>Purpose: Chemical: Conclude on the bioaccumulative potential of the active substance or product. Derivation of bioconcentration factors, clearance time and nature of residues from the submitted endpoint studies.</p>

ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP v1.2 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.AdministrativeDataSummary
Key value for safety assessment		Header 1	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa
Bioconcentration in fish			ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.Bioc

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			oncentrationFish.ParentMetalite
Substance		Entity reference field	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.Substance
logPo/w	Indicate the value for logPo/w and the pH of the substance when measured.	Text	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.LogPow
BCF (aquatic species)	Indicate the value of BCF in total wet weight/normalised to 5% lipid content and the tissue where it was measured (e.g. whole fish, edible tissue, non-edible tissue). Specify further information such as kinetic, steady state, growth corrected; whether the BCF is based on total radioactive residue or parent substance in the remark field.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.BcfAquaticSpecies
Clearance time CT50	Indicate the clearance times in days (d) (CT50). In case the clearance takes place in less than a day (e.g. 22 hr), indicate the hours (h).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.CtFiftyClearanceTime
Clearance time CT90	Indicate the clearance times in days (d) (CT90). In case the clearance takes place in less than a day (e.g. 22 hr), indicate the hours (h).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.CtNinetyClearanceTime
Nature and level of residues	Indicate the level and nature of residues (%) in organisms after the 14-day depuration phase.	Rich text area	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.NatureAndLevelOfResidues
Remarks		Text area	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.Remarks
Bioconcentration in fish			

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BMF in fish (dimensionless)	Report the biomagnification (BMF) factor in fish as the relative concentration (lipid normalised) in a predatory animal compared with the concentration in its prey (BMF = Cpredator/Cprey).	Decimal	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.FishBmf
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.Discussion

10.2.7 Further testing on aquatic organisms – Endpoint study record

<p>Purpose: The bioconcentration in fish of purified active substance shall be determined and the steady-state bioconcentration factors, uptake rate constants and depuration rate constants, incomplete excretion, metabolites formed in fish and, if available, information on organ-specific accumulation shall be reported. Bioconcentration factors shall be expressed as a function of both total wet weight and of the lipid content of the fish.</p> <p>Especially tests shall be provided for substances:</p> <ul style="list-style-type: none"> - with log KOW > 3 - if there are other indications of bioconcentration considered stable (< 90% loss of the original substance via hydrolysis over 24 h)
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ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment v.7.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.DataSource
Materials and methods	Material and methods – common block Applicable Test guideline:	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods

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	EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4)		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestMaterials.Radiolabelling
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestOrganisms
Test organisms (species)	Select species from picklist. If not available, select 'other' and enter name of organism (species).	Open list	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Details on test organisms	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms

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Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion
Lipid content	Indicate the lipid content of test organisms with unit. If appropriate specify the time point at which the measurement was made, e.g. start or end of experiment. Copy this block of fields if measuring lipid content at end of uptake and end of depuration phases. Copy this block of fields for specifying the lipid content ratio in % if required.		ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.LipidContent
Lipid content	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.LipidContent.LipidContent

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	is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
Time point	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.LipidContent.Time Point
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.LipidContent.RemarksOnResults
Lipid content			
Bioaccumulation factor	This repeatable block of fields allows reporting of the aqueous bioconcentration factors, i.e. the steady-state BCFs and/or the kinetic		ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.BioaccumulationFactor

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	<p>BCFk. For sediment-dwelling organisms BAF (bioaccumulation factor), BSAF (biota-sediment accumulation factor) and/or pore water BCFs can be specified. Also dietary biomagnifications factors (BMF), e.g. from fish dietary studies, can be recorded. For dietary biomagnification factor (dietary BMF) according to the OECD 305 part III test, the calculated assimilation efficiency (α) should also be stated. As appropriate or requested by the regulatory programme include table(s) in the rich text field 'Any other information on results incl. tables' showing the bioaccumulation/ bioconcentration factors measured at different time points and concentrations in the water. Upload</p>		
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	<p>predefined or other appropriate table(s) if any, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>	Check box	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result.sAndDiscussion.BioaccumulationFactor.KeyResult</p>
Conc. / dose	<p>Give the concentration in surrounding water (and/or sediment, if sediment study) or the dose level applied (if feeding study). If more than one concentration or dose was tested for which different bioaccumulation factors are reported, e.g. for high and low</p>	Range with open list (Decimal)	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result.sAndDiscussion.BioaccumulationFactor.ConcInEnvironmentDose</p>

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	concentration levels, multiply this block of fields.		
Temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.BioaccumulationFactor.Temp
pH	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.BioaccumulationFactor.Ph
Type	Indicate the reported bioaccumulation value, i.e. either BCF (bioconcentration factor which accounts for substance intake from the surrounding water or pore water if sediment study only), BAF (bioaccumulation factor which accounts for substance intake from both food and surrounding water/sediment),	Open list	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.BioaccumulationFactor.Type

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	BSAF (biota-sediment accumulation factor), BMF (dietary biomagnification factor, i.e. the ratio between the relative concentration in a predatory animal and the concentration in (part of) its prey or the kinetically derived value) or other (to be specified).		
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.BioaccumulationFactor.Value
Basis	From drop-down list, select the basis for the bioaccumulation value, i.e. expressed in relation to the whole body, the total lipid content or specific tissues	Open list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.BioaccumulationFactor.Basis

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	of the test organisms (w.w. = wet weight; d.w. = dry weight). Note: For OECD TG 305-III dietary method, the result is reported relative to the ratio of fish lipid: food lipid.		
Time of plateau	If applicable, indicate time at which plateau was reached (for tissue concentration).	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.BioaccumulationFactor.TimeOfPlateau
Calculation basis	If the Bioaccumulation value was not calculated at steady state, select 'kinetic:' and briefly specify using the supplementary remarks field (e.g. 'kinetic: steady state at 80% of equilibrium' or, for the dietary exposure OECD 305 method, the values of assimilation efficiency, fish concentration at end of depuration etc used in the calculations).	Open list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.BioaccumulationFactor.CalculationBasis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.BioaccumulationFactor.RemarksOnResults

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	<p>to or if no numeric value(s) were derived;</p> <ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:', e.g. for indicating if bioconcentration / bioaccumulation is based on parent compound instead of radioactivity. 		
Bioaccumulation factor			
Depuration	<p>Indicate if clearance of test substance or metabolites from test organisms was observed; give depuration time required for clearance of 50% (DT50), 90% (DT90) and or any other percent of residues.</p>		<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for</p>	<p>Check box</p>	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration.KeyResult</p>

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	hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.		
Elimination	Indicate whether elimination of test substance or metabolites occurred or not.	Closed list	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration.Elimination
Parameter	Indicate to which endpoint type the effect concentration refers, e.g. DT50.	Open list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration.Endpoint
Depuration time (DT)	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration.DepurationTime
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration.RemarksOnResults

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	- entering any additional information by selecting 'other:'.		
Depuration			
Rate constants	Provide the numeric values of relevant rate constants as appropriate and/or give an explanation in field 'Explanation of result'.		ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.RateConstants
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.RateConstants.KeyResult
Rate constant	Select the rate constant, e.g. 'growth rate constant (d-1)'. Additional free text explanation can be entered in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.RateConstants.RateConstant
Value	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.RateConstants.Value

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<p>Remarks on result</p>	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'. 	<p>Open list with remarks (2000)</p>	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.RateConstants.RemarksOnResults</p>
<p>Rate constants</p>			
<p>Details on kinetic parameters</p>	<p>Give values (including 95 % confidence limits and standard deviations) for the uptake and depuration rate constants (all expressed in relation to whole body, total lipid content or specific tissues of the test organisms); give relevant details on computation/data analysis.</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.KineticParameters</p>

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<p>Metabolites</p>	<p>If identified, include table(s) in the rich text field 'Any other information on results incl. tables' with data on any metabolites of the test substance accumulated in test organisms (total) and specific tissues thereof (e.g. lipid) (at least those, accounting for > 10 % of residues). Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Metabolites</p>
<p>Results with reference substance (positive control)</p>	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.ResultsWithReferenceSubstance</p>
<p>Details on results</p>	<p>Report any other relevant results using freetext template as appropriate. Indicate any results related to the chemical properties of the test material. Compare the results for the test substance with that</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.DetailsOnResults</p>

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	for the reference substance. Upload predefined or other appropriate tables(s) if any, and tailor it/them to your needs.		
Reported statistics	Indicate the parameters analysed, the statistical method used and the statistical test performed.	Multi-line text	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.Result sAndDiscussion.ReportedStatistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.Result sAndDiscussion.AnyOtherInformati onOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.Overal lRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.Applic antSummaryAndConclusion
Validity criteria fulfilled	State whether validity criteria in the test guideline have been fulfilled or not. Use supplementary remarks field to state the criteria and supporting information. Clearly indicate if the criteria used are not consistent with those given by the test guideline. If so, give	Closed list with remarks	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.Applic antSummaryAndConclusion.Validity CriteriaFulfilled

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	justification in field 'Rationale for reliability incl. deficiencies' as to why this study summary is considered reliable.		
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10.3 Effect on arthropods including bees - Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g.:</p> <ul style="list-style-type: none"> - Group: Specify species; - Route/time-scale - Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects); - Test type (laboratory/others); - Dose (kg /ha).

ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP – v.1.2 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa
Short-term toxicity to terrestrial/soil arthropods			ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods
Study name / type	Select the study from which the endpoint was derived	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.Link

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Animal group	Select the taxa for which the endpoint below was derived according to the classification given in data requirements (e.g. bees, soil dwelling arthropods and other non-target terrestrial arthropods).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.AnimalGroup
Test organisms (species)	Select species from picklist. If not available, select 'other' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.BasisForEffect
Dose descriptor	Select the dose descriptor(s) associated to the endpoint assessed. If it is a corrected value, please indicate why.	Open list	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.EffectConcentration

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	field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. Select the relevant units e.g µg/bee or CFU/bee.		
Short-term toxicity to terrestrial/soil arthropods			
Long-term toxicity to terrestrial/soil arthropods			ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods
Study name / type	Select the study from which the endpoint was derived	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.Link
Animal group	Select the taxa for which the endpoint below was derived according to the classification given in data requirements (e.g. bees, soil dwelling arthropods and other non-target terrestrial arthropods).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.AnimalGroup
Test organisms (species)	Select the species from the picklist. If not available, select 'other:' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.ParentMetabolite

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Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.Substance
Basis for effect	Select the type of effect for endpoint(s) setting from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.BasisForEffect
Dose descriptor	Select the dose descriptor(s) associated to the endpoint assessed. If it is a corrected value, please indicate why.	Open list	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable Select the relevant units e.g $\mu\text{g}/\text{bee}/\text{day}$, $\mu\text{g}/\text{larva}/\text{developmental period}$ or g/ha Also, for micro-organisms, average achieved dose in colony forming units (cfu) must be reported.	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.EffectConcentration
Long-term toxicity to terrestrial/soil arthropods			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling)	Header 1	ENDPOINT_SUMMARY.ToxicityTerrestrialArthro

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	or field studies for the different taxa). Is there potential for accumulative toxicity		Pods_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.HigherTierTesting.field1350

Links to support material:

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) 10.2903/j.efsa.2013.3295

Candolfi et al (2001). Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products With Non-Target Arthropods: From the Escort 2 Workshop (European Standard Characteristics of Non-Target Arthropod Regulatory Testing). SETAC press, pp 46. ISBN 1-880611-52-x.

Alix et al, 2012. ESCORT 3 – linking non-target arthropod testing and risk assessment with protection goals. CRC SETAC Press, 1–151.

Schaeffer et al (2017): Semi-Field Methods for the Environmental Risk Assessment of Pesticides in Soil, CRC Press

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10.3 Effect on arthropods including bees - Endpoint study record

Purpose

Bees

Information on toxicity, infectiveness and pathogenicity to bees must be reported. Effects on bees shall be assessed and the risk evaluated, including the risk deriving from residues of the active substance or its metabolites in nectar, pollen and water, including guttation.

- A test for acute oral toxicity shall be provided establishing the acute LD₅₀ values together with the NOEC. Sub-lethal effects, if observed, shall be reported.
- A test for acute contact toxicity shall be provided establishing the acute LD₅₀ values together with the NOEC. Sub-lethal effects, if observed, shall be reported.
- A test for chronic toxicity to bees shall be provided establishing the chronic oral EC₁₀, EC₂₀, EC₅₀ together with the NOEC. Where the chronic oral EC₁₀, EC₂₀, EC₅₀ cannot be estimated, an explanation shall be provided. Sub-lethal effects, if observed, shall be reported.
- A bee brood study shall be conducted to determine effects on honeybee development and brood activity. The bee brood study shall provide sufficient information to evaluate possible risks from the active substance on honeybee larvae.
- The test shall provide the EC₁₀, EC₂₀ and EC₅₀ for adult bees, where possible, and larvae together with the NOEC. Where EC₁₀, EC₂₀, EC₅₀ cannot be estimated, an explanation shall be provided. Sub-lethal effects, if observed, shall be reported.
- Tests investigating sub-lethal effects, such as behavioural and reproductive effects, on bees and, where applicable, on colonies may be required.

Non-target arthropods other than bees

Information on toxicity, infectiveness and pathogenicity to arthropods other than bees must be reported. The selection of the test species should be related to the potential use of the plant protection products (e.g. foliar or soil application). Special attention should be given to organisms used for biological control and organisms playing an important role in integrated pest management. Effects on non-target terrestrial arthropods shall be investigated for all active substances except where plant protection products containing the active substance are for exclusive use in situations where non-target arthropods are not exposed.

A test shall provide sufficient information to evaluate the toxicity in terms of LR50 and NOEC of the active substance to *Aphidius rhopalosiphi*.

A test shall provide sufficient information to evaluate the toxicity in terms of LR50 and NOEC of the active substance to *Typhlodromus pyri*.

ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods – v.7.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: EPPO Standard PP1/170 (4): Test methods for evaluating the side-effects of plant protection products on honeybees OECD Test Guideline 213: Honeybees, Acute Oral Toxicity Test OECD Test Guideline 247: Bumblebee, Acute Oral Toxicity Test OECD Test Guideline 214: Honeybees, Acute Contact Toxicity Test OECD Test Guideline 246: Bumblebee, Acute Contact Toxicity Test OECD Test Guideline No. 237 - Honey Bee (Apis Mellifera) Larval Toxicity Test, Single Exposure OECD Series on Testing & Assessment No. 239; Guidance Document on Honey Bee Larval Toxicity Test following Repeated Exposure M.P. Candolfi, S. Blümel, R. Forster et al. (2000): Guidelines to evaluate side-effects of	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods

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	plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative. ISBN: 92-9067-129-7. OPPTS 885.4380 Honey Bee Testing, Tier I OPPTS 885.4340 Nontarget Insect Testing, Tier I		
Application method	Select as method of application as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.ApplicationMethod
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestOrganisms
Test organisms (species)	Select species from picklist. If not available, select 'other' and enter name of organism (species).	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Animal group	Indicate the animal group, e.g.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrest

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	'Hymenoptera (honeybees)' for honeybees or 'Collembola (soil-dwelling springtail)' for a test with <i>Folsomia candida</i> . Helpful for searching purposes.		rialArthropods.MaterialsAndMethods.TestOrganisms.AnimalGroup
Details on test organisms	Enter any details that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions BLOCK (OHT: Terrestrial tox.) Nominal and measured concentrations : For microorganisms average achieved dose in colony forming units (cfu) must be reported.	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion
Toxic reference	Specify the toxic reference considered in the study.	Text area	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsA

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			ndDiscussion.ToxicReference
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.NominalMeasured

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	weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.		
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as behaviour, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectCon

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	<p>numeric value(s) were derived;</p> <ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>		<p>centrations.RemarksOn Results</p>
Effect concentrations			
Details on results	<p>For microorganisms indicate that information on toxicity, infectiveness and pathogenicity to bees and arthropods other than bees must be</p>	Text template	<p>ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.ResultsDetails</p>

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	<p>reported. The text from the US EPA guideline could also be included afterwards. The guideline should be cited (885.4340 - Nontarget Insect Testing, Tier I (February 1996)).</p> <p>Briefly summarise relevant observations and any dose response relationship. Depending on the type of study, select appropriate freetext template (i.e. soil or above-ground arthropods or honeybees) and delete/add elements as appropriate.</p> <p>Include the following information, for bees (pollinators): Lower tier - LD50 and NOED values and potentially differentiate between the types of test (i.e. acute oral, acute contact, chronic and life stage (adult / larvae), the species)) Higher tier – could have fields to indicate the major effects e.g. mortality, behaviour, brood development and colony strength but also could just have the standard text fields (Key Information, Additional information). The residue measurements/pollen</p>		
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	<p>characterisation (to guarantee the proper exposure).</p> <p>Information on Non-target arthropods: Lower tier: EC50, LR50, ER50 values (separate section or separate summary), type of exposure, species (For this type of studies optional reporting of NOEC).</p> <p>Higher tier: EC50, LR50, ER50, NOAER, NOER values (separate section or separate summary), type of exposure, species. (For this type of studies optional reporting of NOEC).</p> <p>Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Ability to record multiple endpoint values (we can have different species, populations, communities etc.)</p>		
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	<p>For microorganisms - The most appropriate end-point for protozoan diseases for determining pathogenic effects is the presence of the vegetative stages (shizonts or meronts) in the tissues of nontarget insects; Mortality time, expressed as LT50 (time course of population mortality), is considered the most reliable parameter for bioassaying fungi of insects in the laboratory</p> <p>Relevant information to record for higher tier. Study site/location, irrigation or other application techniques, sampling method, crop rotation in field study, as well as the field history concerning agricultural management (including PPPs) should be reported.</p>		
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.ResultsReferenceSubstance
Reported statistics and error estimates	<p>Indicate the parameters analysed, the statistical</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToTerrest

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	method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.		rialArthropods.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ApplicantSummaryAndConclusion

10.4 Effects on non-target soil meso- and macrofauna - Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details.</p> <ul style="list-style-type: none"> - Group: Specify species; - Route/time-scale - Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects); - Test type (laboratory/others); - Dose (kg /ha).

ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP – v.1.2 (Final) [October 2020]			
Name	Instructions	Data type	Field path

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Administrative data	Administrative data summary – common block Description of key information example: -“Chronic toxicity to annelids: EC ₅₀ reproduction >=2000 a.s. mg/kg soil dw for <i>Eisenia fetida</i> (OECD 222; Chronic)”	Header 1	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment	Section specific for reporting of tier 1 studies.	Header 1	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa
Short-term toxicity to soil macroorganisms except arthropods	Short term (acute) studies to soil macroorganisms are no longer required.		ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms
Study name / type	Select the study from which the endpoint was derived.	Endpoint reference field	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.Link
Animal group	Indicate the taxa for which the endpoint below was derived according to the classification given in the data requirements (e.g. earthworms).	Multi-line text	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.AnimalGroup
Test organisms (species)	Select the species from the picklist. If not available, select 'other:' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.Substance

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Details on preparation and application of test substance	Provide details on the form the substance was applied in the test.	Rich text area	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.PreparationApplicationTestSubstance
Basis for effect	Select the type of effect for endpoint(s) setting from the picklist. If not available, select 'other' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (EC50 or LC50).	Closed list	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In mg a.s./kg d.w.soil (mg a.s/ha). For micro-organisms, average achieved dose in colony forming units (cfu) also must be reported.	Range with open list (Decimal)	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.EffectConcentration
Short-term toxicity to soil macroorganisms except arthropods			
Long-term toxicity to soil macroorganisms except arthropods			ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms
Study name / type	Select the study from which the endpoint was derived.	Endpoint reference	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.L

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		nce field	ongTermToxicitySoilOrganisms.Link
Animal group	Indicate the taxa for which the endpoint below was derived according to the classification given in the requirements (e.g. earthworms).	Multi-line text	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.AnimalGroup
Test organisms (species)	Select species from the picklist. If not available, select 'other:' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.Substance
Details on preparation and application of test substance	Provide details on how the substance was applied in the test (e.g. soil incorporation, mixed into the soil).	Rich text area	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.PreparationApplicationTestSubstance
Basis for effect	Select the type of effect for endpoint(s) setting from picklist. If not available, select 'other' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (e.g. "EC10, EC20, NOEC.	Open list	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields	Half-bound ed with	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.L

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	together with the appropriate qualifier(s), if applicable. In mg a.s./kg d.w.soil (mg a.s/ha). For micro-organisms average achieved dose in colony forming units (cfu) must be reported.	open list (Decimal)	ongTermToxicitySoilOrganisms.EffectConcentration
Long-term toxicity to soil macroorganisms except arthropods			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.Discussion

Links to support material:

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

10.4 Effects on non-target soil meso- and macrofauna - Endpoint study record

Purpose

A test shall provide information on the effects on growth, reproduction and behaviour of the earthworm.
 Testing shall determine a dose-response relationship and the EC₁₀, EC₂₀ and NOEC shall enable the risk assessment to be conducted in accordance with the appropriate risk quotient analysis, taking into account likely exposure, the organic carbon content (foc) of the test medium and the lipophilic properties (Kow) of the test substance.
 Information on toxicity, infectiveness and pathogenicity to earthworms must be reported.

ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods – v.6.3 (Final) [September 2020]

Name	Instructions	Data type	Field path
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Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 222: Earthworm Reproduction Test (<i>Eisenia fetida</i> / <i>Eisenia andrei</i>) ISO 11268-3:2014: Soil quality - Effects of pollutants on earthworms - Part 3: Guidance on the determination of effects in field situations ISO 23611-1:2018: Soil quality - Sampling of soil invertebrates - Part 1: Hand-sorting and extraction of earthworms	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestOrganisms

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Test organisms (species)	Select species from the picklist. If not available, select 'other' and enter the species name of the test organism.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Animal group	Indicate the animal group, e.g. 'annelids' for a test with a worm species. Helpful for searching purposes.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestOrganisms.AnimalGroup
Details on test organisms	Enter any details that could be relevant for evaluating this study summary. Use free-text template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions BLOCK (OHT: Terrestrial tox.) Nominal and measured concentration: Average achieved dose in colony forming units (cfu) must be reported.	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion

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Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn

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	it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.		
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'. Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	Information on toxicity, pathogenicity and infectiveness to earthworms should be reported. Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.ResultsDetails
Results with reference	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDisc

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substance (positive control)	Use freetext template and delete/add elements as appropriate.		ussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.OverallRemarksAttachments
Applicant's summary and conclusion	Applicant's summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ApplicantSummaryAndConclusion

10.5 Effects on soil nitrogen transformation - Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details Chemicals: long term effects on nitrogen transformation Microorganisms: impact on relevant non-target micro-organisms and on their predators (e.g. protozoa for bacterial inoculants)</p>
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ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP – v.1.1 (Final) [October 2020]			
Name	Instructions	Data type	Field path

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Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment
Long-term toxicity to soil microorganisms			ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.Substance
Basis for effect	For chemicals: In line with the OECD test guideline the endpoint should be based on nitrogen transformation rate and not nitrogen levels (e.g. % effect at day xx at mg a.s./kg d.w.soil (mg a.s/ha)). For microorganisms: select other and add remark to report impact on soil microbial communities	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed. If it is a corrected value, please indicate why.	Open list	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.DoseDescriptor
Effect value	Enter % effect at day xx at mg a.s./kg d.w.soil (mg a.s/ha)	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.EffectValue

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Long-term toxicity to soil microorganisms			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.Discussion

Links to support material:

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

10.5 Effects on soil nitrogen transformation - Endpoint study record

Purpose

Impact on relevant non-target micro-organisms and on their predators (e.g. protozoa for bacterial inoculants) shall be reported. Expert judgement is required to decide whether additional studies are necessary. Such decision will take into consideration the available information in this Section and other Sections, in particular data on the specificity of the micro-organism, and the expected exposure. Useful information may also be available from the observations carried out in efficacy testing. Special attention shall be given to organisms used in integrated crop management (ICM).

A test shall provide sufficient data to evaluate the impact of active substances on soil microbial activity, in terms of nitrogen transformation.

ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms – v.6.3 (Final) [September 2020]

Name	Instructions	Data type	Field path
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IUCLID ACTIVE SUBSTANCE APPLICATION MANUAL

Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.Data Source
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.Data Source.Reference
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 216: Soil Microorganisms: Nitrogen Transformation Test OPPTS 850.5100 Soil Microbial Community Toxicity Test	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.Test Materials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.Test Materials.TestMaterial Information
Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.Test Organisms
Test organisms (inoculum)	Select 'soil' if soil samples were used as inoculum. Otherwise select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.Test Organisms.TestOrganismsInoculum

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Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.MaterialsAndMethods.StudyDesign
Test conditions	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value and unit .	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.Effect

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		remarks	tConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Close list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults

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	because of methodological limitations' plus free text, e.g. 'highest concentration tested'.		
Effect concentrations			
Details on results	<p>Report any other relevant results using freetext template as appropriate. As appropriate include table with raw data (use predefined table if any or adapt similar table from study report) and/or attach graph of the dose-response curve.</p> <p>For chemicals: The results of the range-finding test expressed as micrograms of CO₂ evolved per gram of dry soil per hour, and micrograms of each of NH₃ and NO₃ present per gram of dry soil, in treated and untreated samples. If the range-finding test indicated that the highest concentration of the test substance tested (but not less than 1,000 µg/g) had no effect on the test system, report the results by soil source and type and state that the test substance has a low potential for adversely affecting microbial functions in such soils. If the range-finding test indicated a greater than 50 percent reduction of the endpoints of the test at a concentration of the test substance that represents the analytical detection limit (if tested), report the results by soil source and type and state that the test substance is toxic to microbial life in such soils at concentrations at or below the analytical detection limit used in this study.</p> <p>For microorganisms: impact on the soil microbial community should be evaluated</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.ResultsDetails
Results with reference substance (positive control)	Results with reference substance (positive control) - Indicate whether the results with the reference substance(s) are valid.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.Statistics

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Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ApplicantSummaryAndConclusion

10.6 Effects on terrestrial non-target higher plants - Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g., effects on seedling emergence and/or vegetative vigour.</p>

ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP v.1.3			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.AdministrativeDataSummary
Key value for safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa
Toxicity to terrestrial plants			ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants
Study name / type		Endpoint reference field	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueC

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			sa.ToxTerrestrialPlants. Link
Type of study	Select the study from which the endpoint was derived	Closed list	ENDPOINT_SUMMARY. ToxicityToTerrestrialPlants_EU_PPP.KeyValueC sa.ToxTerrestrialPlants. TypeOfStudy
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY. ToxicityToTerrestrialPlants_EU_PPP.KeyValueC sa.ToxTerrestrialPlants. TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY. ToxicityToTerrestrialPlants_EU_PPP.KeyValueC sa.ToxTerrestrialPlants. ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY. ToxicityToTerrestrialPlants_EU_PPP.KeyValueC sa.ToxTerrestrialPlants. Substance
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Multi select open list with remarks	ENDPOINT_SUMMARY. ToxicityToTerrestrialPlants_EU_PPP.KeyValueC sa.ToxTerrestrialPlants. BasisForEffect
Dose descriptor	Select the dose descriptor associated to the endpoint assessed (e.g. ER10, ER50) .	Open list	ENDPOINT_SUMMARY. ToxicityToTerrestrialPlants_EU_PPP.KeyValueC sa.ToxTerrestrialPlants. DoseDescriptor
Effect concentration	Report value in g/ha	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY. ToxicityToTerrestrialPlants_EU_PPP.KeyValueC sa.ToxTerrestrialPlants. EffectConcentration
Toxicity to terrestrial plants			

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Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. semi-field or field studies).	Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.Discussion

Links to support material

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-

10.6 Effects on terrestrial non-target higher plants - Endpoint study record

Purpose:

A test shall provide the ER₅₀ values of the active substance to non-target plants
The information provided shall be sufficient to permit the evaluation of effects of the active substance on non-target plants.

ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants – v.6.4 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods

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	OECD Test Guideline 227: Terrestrial Plant Test: Vegetative Vigour Test OPPTS 885.4300 - Nontarget Plant Studies, Tier I		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.SamplingAndAnalysis
Test organisms	Indicate the species and corresponding plant group. As appropriate you can prepare a study summary for each species used in a given study or cover all species tested in one record. In the latter case, copy this field block and enter the information required for each species.	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestOrganisms
			ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestOrganisms.TestOrganisms
Species	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestOrganisms.TestOrganisms.Species
Plant group	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestOrganisms.TestOrganisms.PlantGroup
Details on test	For robust study summaries or as requested by the regulatory programme, also include relevant details on	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.Mater

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organisms	the test organism in the respective subfield. Use freetext template and delete/add elements as appropriate.		ialsAndMethods.TestOrganisms.TestOrganisms.DetailsOnTestOrganisms
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.KeyResult
Species	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.Species
Duration	Enter numeric value.	Unit meas	ENDPOINT_STUDY_RECORD.ToxicityToT

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		ure with Closed List (Decimal)	errestrialPlants.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.Effect

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	<p>entering free text explanation in the supplementary remarks field; or</p> <p>- entering any additional information on the effect level by selecting 'other:'</p> <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>	(2000)	ctConcentrations.RemarksOnResults
Effect concentrations			
Details on results	<p>Observations and reporting 885.4300 - Nontarget Plant Studies, Tier I (February 1996):</p> <p>Any abnormal adverse or beneficial effects in treatment and/or control groups, including dates and times the effects were observed.</p> <p>Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any available, and tailor it/them to your needs or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>As appropriate also attach a figure with growth curves in field 'Attached background material'.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.ResultsDetails
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	<p>Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.Statistics

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	with the determination of concentration-response relationship.		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ApplicantSummaryAndConclusion

10.7 Effects on other terrestrial and aquatic organisms (flora and fauna)- Endpoint summary

Purpose	Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details.
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ENDPOINT_SUMMARY.AdditionalEcotoxicologicalInformation v.3.0			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.AdditionalEcotoxicologicalInformation.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AdditionalEcotoxicologicalInformation.Discussion

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10.7 Effects on other terrestrial and aquatic organisms (flora and fauna) - Endpoint study record

Purpose

The additional studies might include further acute studies on additional species or processes or higher tier studies such as chronic, sub-lethal or reproductive studies on selected non-target organisms.

Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation v.6.3

Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.ApplicantSummaryAndConclusion

10.8 Monitoring data – Endpoint summary

Purpose:

Available monitoring data concerning effects of the active substance/plant protection product to non-target organisms shall be reported.

ENDPOINT_SUMMARY.BiologicalEffectsMonitoring v.3.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BiologicalEffectsMonitoring.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.BiologicalEffectsMonitoring.Discussion

10.8 Monitoring data – Endpoint study record

Purpose:

Summary information of the most relevant findings should be reported.
Enter a short description of the most relevant endpoint data. The short description could include for example:

- used method
- organism monitored
- related test conditions
- final results

ENDPOINT_STUDY_RECORD.BiologicalEffectsMonitoring v.6.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path

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Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.Administrati veData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.MaterialsAn dMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.MaterialsAn dMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.MaterialsAn dMethods.AnyOtherInfo rminationOnMaterialsAnd MethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.ResultsAndD iscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.ResultsAndD iscussion.AnyOtherInfor mationOnResultsInclTa bles
Overall remarks, attachments		Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.OverallRema rksAttachments
Overall remarks	Overall remarks, attachments – common block	Rich text area	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.OverallRema rksAttachments.Remark sOnResults
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.ApplicantSu mmaryAndConclusion

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11 Literature data and change log

11.1 Literature data

<p>Purpose: Description of the methodology used for the search for all relevant data from scientific peer reviewed open literature List of all relevant studies retrieved</p>
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FLEXIBLE_RECORD.LiteratureSearch – v.5.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Header 1	FLEXIBLE_RECORD.LiteratureSearch.AdministrativeData
		Confidentiality	FLEXIBLE_RECORD.LiteratureSearch.AdministrativeData.DataProtection
Link to relevant studies	<p>Link to all Literature Reference entities that were retrieved from the literature search and are considered relevant and reliable after the full text screening step.</p> <p>An appropriate Endpoint Study Record should be completed for each relevant study and the literature reference included in the data source section.</p>	Header 1	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies
Literature reference(s)		Literature reference list	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.LiteratureReference
Description of key information	Summary of all relevant data from the scientific peer reviewed open literature on the active substance, metabolites	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.KeyInformationDesc

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	and breakdown or reaction products and plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species		
Overall summary of the literature search	<p>Summary of the methodology used to retrieve relevant studies on side-effects on health, the environment and non-target species.</p> <p>Report the criteria used to classify the references as being clearly non-relevant (e.g. not related to pesticides).</p> <p>Report the criteria used to assess the reliability of the studies.</p>	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.SearchSummary
Search strategy	Indicate how the literature search was carried out.	Header 1	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy
Bibliographic databases used in the literature review and search results	A description each of the search strategies used in the literature review		FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed
Online search service	Select the database/source where the search was performed. Use other to indicate a database/source that is not included in the list. The remarks field should contain the justification for selecting the database/source. More	Open list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.SearchService

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	information on databases/sources Is provided in the supporting materials below		
Date of search	Provide the date when the search was performed using the database.	Date	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Date
Time window of the literature search	The period covered in the literature search e.g. 2010 to 2020	Text	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.TimeWindow
Search string(s) used	<p>The search strings used to retrieve the records e.g.</p> <ol style="list-style-type: none"> 1. ts=Chlorpyrifos 2. ts=(Brodan or Detmol or Dowco 179 or Dursban or eradex or Lorsban or Paqeant or Piridane) 3. ts=((scout or stipend or empire) and (pesticide* or insect*)) 4. #3 OR #2 OR #1 <p>More examples are provided in the supporting materials below</p>	Multi-line text	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Strings
Filters	Indicate if filters were applied in the search. If yes is selected the filters applied must be described	Closed list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Filters
Limits	Indicate if any limits were applied in the search, for example only studies in English. If yes is the limits applied must be described	Closed list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Limits

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Number of hits	The number of hits for the search in each database/source	Integer	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.NoHits
Number of hits after refinement	The number of hits after refinement, if applicable	Integer	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.NoHitsRefinement
Number of hits after duplicate removal	The number of hits after duplicate removal	Integer	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.NoHitsDuplicate
Bibliographic databases used in the literature review and search results			
Evaluation of the review		Header 1	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview
Records retrieved	The number of records retrieved when the results for the searches above where combined	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.RecordsRetrieved
Records after removal of duplicates	Total number of summary records retrieved after removing duplicates from all database searches	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoAfterDuplicates
Records after rapid assessment	Report the number of records retained after title/abstract screening	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoRapidAssessment
Records after detailed assessment	Report the number of records retained after full text screening	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoDetailedAssessment
Reliable studies	Report the number of records retained after the reliability assessment	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ReliableStudies
Evaluated studies	Number of studies included in the dossier, reported in an endpoint study record and used	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.EvaluatedStudies

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	as supporting information. These studies should be listed in the Literature reference(s) field and the number should be the same.		
Publications excluded from the risk assessment after detailed assessment of full-text documents	For each of the studies excluded on the basis of relevance or reliability link to the Literature Reference entity and describe the reason for exclusion		FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications
Literature reference	Link a reference to the excluded publication.	Literature reference list	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications.LitReference
Exclusion reason	Reason for not including publication in dossier (based on relevance and reliability criteria).	Multi-line text	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications.ExclusionReason
Publications excluded from the risk assessment after detailed assessment of full-text documents	For each of the studies excluded on the basis of relevance or reliability link to the Literature Reference entity and describe the reason for exclusion		
Additional information		Header 1	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation
Additional information	Any other information needed to interpret the results for the literature research	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.AdditionalInfo
Attached background material	Upload supporting files e.g bibliographic metadata		FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial
Attached document	Upload file by clicking the upload icon. The bibliographic results of	Single file attachment	FLEXIBLE_RECORD.LiteratureSearch.Additional

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	literature searches can be uploaded here in RIS format or as an Excel table containing bibliographic information.		Information.Background dMaterial.Attachment
Remarks	Indicate the source of the contents of the file and the format type.	Text	FLEXIBLE_RECORD.Lite ratureSearch.Additional Information.Background dMaterial.Remarks
Attached background material			

Link to support material:

Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009
 Further guidance on performing and presenting the literature search
 Inventory of Sources of Scientific Evidence Relevant to EFSA's Risk [Technical Manual for Performing Electronic Literature Searches in Food and Feed Safety](#)

Additional considerations:

The applicant must ensure that terms and conditions asserted by any copyright holder of publications or information submitted to EFSA are fully satisfied. The applicant should consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The applicant remains solely responsible and liable for obtaining all necessary authorisations and rights to use, reproduce and share the publications provided to EFSA

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11.2 Change log

Purpose

According to Article 6(2k) of COMMISSION IMPLEMENTING REGULATION (EU) 2020/1740, the renewal dossier shall include a checklist demonstrating that the renewal dossier is complete in view of the uses applied for and indicating which data are new

To facilitate the automated generation of list of test and study report – ‘Previously used’

All study reports for the active substance and product that were part of the approval or subsequent renewals must be included in the dossier

FLEXIBLE_RECORD.ChangeLog – v.1.0 (Final) [September 2020]

Name	Instructions	Data type	Field path
General information		Header 1	FLEXIBLE_RECORD.ChangeLog.GeneralInformation
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.ChangeLog.GeneralInformation.field7767
Summary	Provide any additional explanation needed in order to facilitate the compilation of the final list of the tests and studies relied upon and whether the study was already submitted in the framework of national authorizations. 2 See Art.3 of Annex of Regulation No 283/2013 and 284/2013	Rich text area	FLEXIBLE_RECORD.ChangeLog.GeneralInformation.Summary
Change log		Header 1	FLEXIBLE_RECORD.ChangeLog.ChangeLog
Change log entries	Create an entry in the table for each test or study		FLEXIBLE_RECORD.ChangeLog.ChangeLog.ChangeLogEntries
Link to document	Select each of the IUCLID documents included in the dataset	Endpoint reference field	FLEXIBLE_RECORD.ChangeLog.ChangeLog.ChangeLogEntries.LinkToDocument

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Status	For each of the documents indicate if the document is 'new', 'previously used' 'obsolete' or 'updated'	Closed list	FLEXIBLE_RECORD.ChangeLog.ChangeLog.ChangeLogEntries.Status
Remark	In the remark indicate for which data point the study has been previously used	Multi-line text	FLEXIBLE_RECORD.ChangeLog.ChangeLog.ChangeLogEntries.Remark
Change log entries			

Link to support material:

GUIDANCE DOCUMENT ON PREPARING LISTS OF TEST AND STUDY REPORTS ACCORDING TO ARTICLE 60 OF REGULATION (EC) No 1107/2009 (SANCO/12580/2012– rev. 3.1)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_12580.pdf

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1740

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R1740>

12 Classification and labelling – Flexible record

Purpose:

Proposals for the classification and labelling of the active substance in accordance with Regulation (EC) No 1272/2008 shall be submitted and justified, including:

- pictograms,
- signal words,
- hazard statements, and precautionary statements.

FLEXIBLE_RECORD.Ghs v6.5 (Final)			
Name	Instructions	Data type	Field path
	Set the confidentiality/regulatory purpose information for each individual record created .	Confidentiality	FLEXIBLE_RECORD.Ghs.DataProtection
General Information		Header 1	FLEXIBLE_RECORD.Ghs.GeneralInformation
Name	When a Substance or a Mixture has more than one	Text	FLEXIBLE_RECORD.Ghs.GeneralInformation.Name

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	<p>classification and labelling record it is recommended to specify a name for each individual record so that they can be easily identified (e.g. 'classification with more/equal 0.1% of substance C' and 'classification with less than 0.1% of substance C').</p>		
Not classified	<p>Select this checkbox if your Substance or Mixture is not classified.</p>	Check box	FLEXIBLE_RECORD.Ghs.GeneralInformation.Not Classified
Implementation	<p>The GHS implementation can be different depending on certain regions (e.g. EU, Japan, Australia). Specify the Implementation by selecting from the drop-down list. If none of the pre-defined items applies, select 'other:'. A text field is then activated next to the list field in</p>	Open list	FLEXIBLE_RECORD.Ghs.GeneralInformation.Implementation

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	which you can enter any freetext. If you wish to record a GHS for another region, add a new block.		
Type of classification	Indicate whether the classification is harmonised or if a self-classification is provided.	Closed list	FLEXIBLE_RECORD.Ghs.GeneralInformation.TypeClassification
Remarks	If necessary provide any additional comments here.	Rich text area	FLEXIBLE_RECORD.Ghs.GeneralInformation.Remarks
Related composition		Header 2	FLEXIBLE_RECORD.Ghs.GeneralInformation.RelatedCompositions
Related composition	This section relates to section 1.2 (Composition – Composition ID). It allows links to be created from a classification to one or more compositions of a substance. Related composition is a repeatable block section. Click the green Plus button to add a new repeatable block. The data entry screen appears and an empty block is	Endpoint reference list	FLEXIBLE_RECORD.Ghs.GeneralInformation.RelatedCompositions.Composition

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	now ready to be filled in. Add a new block for each link.		
Classification		Header 1	FLEXIBLE_RECORD.Ghs.Classification
Physical Hazards		Header 2	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.ReasonForNoClassification
Explosives		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.Explosives.ReasonForNoClassification
Flammable gases and chemically unstable gases		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableGases
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableGases.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHa

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			zards.FlammableGases. HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableGases. ReasonForNoClassificati on
Aerosols		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableAerosol s
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableAerosol s.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableAerosol s.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableAerosol s.ReasonForNoClassifica tion
Chemicals under pressure		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.ChemicalsUnderPr essure
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.ChemicalsUnderPr essure.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.ChemicalsUnderPr essure.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.ChemicalsUnderPr essure.ReasonForNoClas sification

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Oxidising gases		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.OxidisingGases
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.OxidisingGases.Ha zardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.OxidisingGases.Ha zardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.OxidisingGases.Re asonForNoClassification
Gases under pressure		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.GasesPres
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.GasesPres.Hazard Category
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.GasesPres.Hazard Statement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.GasesPres.Reason ForNoClassification
Flammable liquids		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableLiquids
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableLiquids. HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableLiquids. HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa

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			zards.FlammableLiquids. ReasonForNoClassification
Flammable solids		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.FlammableSolids
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.FlammableSolids. HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.FlammableSolids. HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.FlammableSolids.R easonForNoClassification
Self-reactive substances and mixtures		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.SelfReactiveSubst Mixt
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.SelfReactiveSubst Mixt.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.SelfReactiveSubst Mixt.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.SelfReactiveSubst Mixt.ReasonForNoClassif ication
Pyrophoric liquids		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.PyrophoricLiquids
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalH azards.PyrophoricLiquids. HazardCategory

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		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricLiquids. HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricLiquids. ReasonForNoClassificati on
Pyrophoric solids		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricSolids
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricSolids.H azardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricSolids.H azardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricSolids.R easonForNoClassificatio n
Self-heating substances and mixtures		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.SelfHeatSubstMixt
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.SelfHeatSubstMixt .HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.SelfHeatSubstMixt .HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.SelfHeatSubstMixt .ReasonForNoClassificati on

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Substances and mixtures which in contact with water emit flammable gases		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.SubstMixtWater
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.SubstMixtWater.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.SubstMixtWater.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.SubstMixtWater.ReasonForNoClassification
Oxidising liquids		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingLiquids
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingLiquids.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingLiquids.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingLiquids.ReasonForNoClassification
Oxidising solids		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingSolids
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingSolids.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHa

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			zards.OxidisingSolids.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.OxidisingSolids.ReasonForNoClassification
Organic peroxides		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.OrganicPeroxides
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.OrganicPeroxides.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.OrganicPeroxides.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.OrganicPeroxides.ReasonForNoClassification
Corrosive to metals		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.CorMetals
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.CorMetals.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.CorMetals.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.CorMetals.ReasonForNoClassification
Desensitized explosives		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard.DesensitizedExplosives
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazard

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			zards.DesensitizedExplosives.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives.ReasonForNoClassification
Health hazards		Header 2	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ReasonForNoClassification
Acute toxicity - oral		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityOral
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityOral.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityOral.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityOral.ReasonForNoClassification
Acute toxicity - dermal		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHaz

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			ards.AcuteToxicityDermal
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityDermal.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityDermal.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityDermal.ReasonForNoClassification
Acute toxicity - inhalation		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityInhalation
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityInhalation.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityInhalation.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityInhalation.ReasonForNoClassification
Skin corrosion / irritation		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Irritation
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Irritation.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Irritation.HazardStatement

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		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.Irritation.ReasonForNoClassification
Serious eye damage / eye irritation		Row label	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.EyeIrritation
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.EyeIrritation.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.EyeIrritation.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.EyeIrritation.ReasonForNoClassification
Respiratory sensitisation		Row label	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.RespiratorySensitisation
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.RespiratorySensitisation.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.RespiratorySensitisation.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.RespiratorySensitisation.ReasonForNoClassification
Skin sensitisation		Row label	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.SkinSensitisation
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.SkinSensitisation.HazardCategory

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		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.SkinSensitisation.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.SkinSensitisation.ReasonForNoClassification
Aspiration hazard		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AspirationHazard
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AspirationHazard.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AspirationHazard.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AspirationHazard.ReasonForNoClassification
Reproductive toxicity		Header 3	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ReproductiveToxicity
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ReproductiveToxicity.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ReproductiveToxicity.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ReproductiveToxicity.ReasonForNoClassification

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Reproductive toxicity		Row label	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.ReasonForNoClassification
Specific effect		Text	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.SpecificEffect
Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.RouteExposure
Effects on or via lactation		Row label	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.Effects
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.Effects.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity

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			y.Effects.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ReproductiveToxicity.Effects.ReasonForNoClassification
Germ cell mutagenicity		Header 3	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.ReasonForNoClassification
Germ cell mutagenicity		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell.ReasonForNoClassification
Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell.RouteExposure

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Carcinogenicity		Header 3	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.ReasonForNoClassification
Carcinogenicity		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity.ReasonForNoClassification
Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity.RouteExposure
Specific target organ toxicity - single (STOT-SE)		Header 3	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle

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			FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.ReasonForNoClassification
Specific target organ toxicity - single (STOT-SE)		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.ReasonForNoClassification
System	Select any specific system where toxicity was observed that is considered of	Open list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.System

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	biological relevance.		
Affected organs	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.AffectedOrgans
Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.RouteExposure
Specific target organ toxicity - repeated (STOT-RE)		Header 3	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated
			FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.ReasonForNoClassification

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Specific target organ toxicity - repeated (STOT-RE)		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.Toxicity
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.Toxicity.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.Toxicity.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.Toxicity.ReasonForNoClassification
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.Toxicity.System
Affected organs	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.Toxicity.AffectedOrgans

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Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.Toxicity.RouteExposure
Specific concentration limits		Header 2	FLEXIBLE_RECORD.Ghs.Classification.SpecificConcentrations
			FLEXIBLE_RECORD.Ghs.Classification.SpecificConcentrations.ConcentrationRange
Concentration range (%)		Range (Decimal)	FLEXIBLE_RECORD.Ghs.Classification.SpecificConcentrations.ConcentrationRange.ConcentrationRangeVal
Hazard categories		Multi select closed list	FLEXIBLE_RECORD.Ghs.Classification.SpecificConcentrations.ConcentrationRange.HazardCategories
Environmental hazards		Header 2	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards
Aquatic environment		Header 3	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.ReasonForNoClassification

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			ntalHazards.AquaticEnvironment.ReasonForNoClassification
Hazardous to the aquatic environment (acute / short-term)		Row label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.AcuteShortTerm
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.AcuteShortTerm.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.AcuteShortTerm.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.AcuteShortTerm.ReasonForNoClassification
Hazardous to the aquatic environment (long-term)		Row label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.LongTerm
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.LongTerm.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.LongTerm.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.LongTerm.ReasonForNoClassification

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M factor		Header 4	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.MFactor
M-Factor acute		Integer	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.MFactor.MFactorAcute
M-Factor chronic		Integer	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.MFactor.MFactorChronic
Ozone layer		Header 3	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.ReasonForNoClassification
Hazardous to the ozone layer		Row label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardousOzone
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardousOzone.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer

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			.HazardousOzone.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardousOzone.ReasonForNoClassification
Additional hazard classes		Header 2	FLEXIBLE_RECORD.Ghs.Classification.AdditionalHazard
Additional hazard classes		Text area	FLEXIBLE_RECORD.Ghs.Classification.AdditionalHazard.Classes
Additional hazard statements		Text area	FLEXIBLE_RECORD.Ghs.Classification.AdditionalHazard.Statements
Labelling		Header 1	FLEXIBLE_RECORD.Ghs.Labelling
Signal word		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.SignalWord
Hazard pictogram		Header 2	FLEXIBLE_RECORD.Ghs.Labelling.HazardPictogramBlock
			FLEXIBLE_RECORD.Ghs.Labelling.HazardPictogramBlock.HazardPictogram
Code		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.HazardPictogramBlock.HazardPictogram.Code
Hazard statements		Header 2	FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock
			FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock.HazardStatements
Hazard statement		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock.HazardStatement

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Additional text		Text	FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock.HazardStatements.AdditionalText
Precautionary statements		Header 2	FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock
			FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock.PrecautionaryStatements
Precautionary statement		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock.PrecautionaryStatements.PrecautionaryStatement
Additional text		Multi-line text	FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock.PrecautionaryStatements.AdditionalText
Additional labelling requirements		Header 2	FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock
Additional non-GHS hazard statements			FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.LabelingRequirements
Additional non-GHS hazard statement		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.LabelingRequirements.SupplHazardStatement
Additional text		Text	FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.LabelingRequirements.AdditionalText
Additional non-GHS hazard statements			

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Additional labelling			FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.AdditionalLabelling
Additional labelling		Text	FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.AdditionalLabelling.Labeling
Additional labelling			
Notes		Header 1	FLEXIBLE_RECORD.Ghs.NotesBlock
			FLEXIBLE_RECORD.Ghs.NotesBlock.Notes
		Closed list	FLEXIBLE_RECORD.Ghs.NotesBlock.Notes.Note

13 Summary and evaluation

Purpose

Summarise the overall conclusions for the substance or mixture

Provide a place to upload files or reports which could not be attached in other sections but are used to support the evaluation.

FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP – v.1.1 (Final) [October 2020]

Name	Instructions	Data type	Field path
Administrative data	See administrative data	Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdministrativeDataSummary
	Use this field to set flags for confidentiality and regulatory purpose(s). Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdministrativeDataSummary.DataProtection
Reports and administrative information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo

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Reports and administrative information			FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo
Type of report	Indicate the type of document that has been uploaded e.g. 'Document C Existing or proposed labels'	Multi-line text	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.TypeOfReport
Attached document	If the file or document uploaded in the 'Attach one or more documents including the sanitised version of the document' contains redacted information upload the original version in this field	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.AttachedDocument
Attached (sanitised) document for publication	<p>Upload sanitised version of files or documents which could not be uploaded in other sections of the dossier. This would include</p> <p>'Document C Existing or proposed labels'</p> <p>'Document G Permission of each formulant in accordance with EU legislation'</p> <p>'Document I Other data on the formulants'</p> <p>Documents M, N and L - report generator should be used to create these documents</p>	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.SanitisedDocument

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	when the appropriate report format (ftl file) is available		
Reports and administrative information			
Other references (including SDS)	<p>Link to other reports not referenced in the endpoint study records needed to support the assessment. The bibliographic information should be completed and the PDF uploaded in the literature reference entity</p> <p>This would include</p> <ul style="list-style-type: none"> 'Safety datasheets' 'Scientific opinions of national/international regulatory bodies' 	Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS
References		Literature reference list	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS.References
Additional information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation
Additional information	Overall summary of the main conclusions for the substance or mixture can be entered here	Rich text area	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation.AdditionalInformation

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Additional considerations

The applicant must ensure that terms and conditions asserted by any copyright holder of publications or information submitted to EFSA are fully satisfied. The applicant should consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The applicant remains solely responsible and liable for obtaining all necessary authorisations and rights to use, reproduce and share the publications provided to EFSA

EU PPP Active substance information

1. Identity of the active substance and applicant

Purpose:

This document facilitates the creation of a substance dataset when completing a mixture/product dossier. It also links to a reference substance in a mixture composition document. This document should be completed for active substance and relevant metabolites and impurities

Note: if there are no studies for a component of mixture link directly to a reference substance.

Substance – v.8.1 (Final)			
Name	Instructions	Type	Field Path
Substance name	The International Organization for Standardization (ISO) common name, or proposed ISO common name	Multi-line text	SUBSTANCE.ChemicalName
Public name	Public name of the active substance	Multi-line text	SUBSTANCE.PublicName
Other substance identifiers	Code numbers used to identify the active substance, during development work, shall be reported. For each code number reported, the material to which it relates, the period for which it was used should be reported in the Remarks field The Member States or other countries in which it was used and is being used, should be reported in the Country field		SUBSTANCE.OtherNames
Flags	See confidentiality	Confidentiality	SUBSTANCE.OtherNames.DataProtection
Identifier		Open list	SUBSTANCE.OtherNames.NameType

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Identity		Multi-line text	SUBSTANCE.OtherNames.Name
Country		Multi select open list	SUBSTANCE.OtherNames.Country
Relation		Open list	SUBSTANCE.OtherNames.Relation
Remarks		Text area	SUBSTANCE.OtherNames.Remarks
Other substance identifiers			
Legal entity flags		Confidentiality	SUBSTANCE.OwnerLegalEntityProtection
Legal entity	Include the name of the legal entity i.e. Company name for the applicant	Entity reference field	SUBSTANCE.OwnerLegalEntity
Third party flags		Confidentiality	SUBSTANCE.ThirdPartyProtection
Third party	Option to link to the legal entity of a third party. This is to be filled in by consultants if they are working on the dossier.	Entity reference field	SUBSTANCE.ThirdParty
Contact persons	Contact entity		SUBSTANCE.ContactPersons
Person flags		Confidentiality	SUBSTANCE.ContactPersons.DataProtection
Person		Entity reference field	SUBSTANCE.ContactPersons.ContactPerson
Contact persons			
Identification of substance		Header 1	SUBSTANCE.ReferenceSubstance
Reference substance flags		Confidentiality	SUBSTANCE.ReferenceSubstance.Protection
Reference substance	Link to the reference substance Reference substance v.6.4 (Final)	Entity reference field	SUBSTANCE.ReferenceSubstance.ReferenceSubstance
Type of substance		Header 1	SUBSTANCE.TypeOfSubstance

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Type of substance	For Microorganism dossiers 'microorganism or toxin produced by microorganism' must be selected. The other types can be used for chemicals	Open list	SUBSTANCE.TypeOfSubstance.Composition
Origin	Picklist to indicate class of active substance e.g organic or inorganic	Open list	SUBSTANCE.TypeOfSubstance.Origin
Role in the supply chain	Check 'Manufacturer' to indicate the applicant is the Producer of the active substance	Header 1	SUBSTANCE.RoleInSupplyChain
Role flags		Confidentiality	SUBSTANCE.RoleInSupplyChain.RoleProtection
Manufacturer		Check box	SUBSTANCE.RoleInSupplyChain.Manufacturer
Importer		Check box	SUBSTANCE.RoleInSupplyChain.Importer
Only representative		Check box	SUBSTANCE.RoleInSupplyChain.OnlyRepresentative
Downstream user		Check box	SUBSTANCE.RoleInSupplyChain.DownstreamUser

Links to support materials

[Legal entity](#)
[ISO/TC 81](#)

1.2 Producer

Purpose

The name and address of the manufacturer of the preparation and of each micro-organism in the preparation must be provided as must the name and address of each manufacturing plant in which the preparation and microorganism are manufactured.

A contact person must be provided for each manufacturer.

FLEXIBLE_RECORD.Suppliers – v.4.0 (Final) [July 2018]			
Name	Instructions	Data Type	Field Path
	Set the confidentiality flag and regulatory purpose. Confidentiality of dossiers submitted via IUCLID - practical	Confidentiality	FLEXIBLE_RECORD.Suppliers.DataProtection

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	instructions for applicants		
Manufacturer / Importer / Formulator		Header 1	FLEXIBLE_RECORD.Suppliers.ManufacturerImportForm
Name	<p>Indicate the name of the Supplier. Click the Link button to select the Supplier and establish the link. If the desired Supplier is not present in your database, click the New button. It will trigger the opening of the Legal entity creation dialogue.</p> <p>The Supplier is created and simultaneously linked to the Substance or Mixture/Product dataset. To complete the information of this newly created Legal entity, click the Goto button</p> <p>The modifications will be automatically updated by clicking the Save button . The Back button button will lead back to section 1.7 Suppliers. The link can be deleted by clicking the Delete button .</p>	Entity reference field	FLEXIBLE_RECORD.Suppliers.ManufacturerImportForm.LegalEntity
Remarks		Text area	FLEXIBLE_RECORD.Suppliers.ManufacturerImportForm.Remarks
Only representation information		Header 1	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo
Assignment from non EU manufacturer	Insert the official assignment documentation from the non EU-	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.NonEUManufacturerAssignment

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	<p>manufacturer. Click the Attachment button and the green Plus button in the context menu appearing. Specify the path and the name of the file to be inserted and indicate any remarks if useful in the Properties window.</p>		
Other importers	<p>The other Importers of the same substance, from the same non EU manufacturer, are considered to be downstream users for the only representative, and if necessary they can be recorded in this table-view block of fields. For each Importer, click the Add row button to create a new row.</p>		FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries
Name	<p>Indicate the name(s) of the other Importer(s), (i.e. the Downstream user(s) under REACH). Click the Link button to select the Supplier and establish the link. If the desired Supplier is not present in your database, click the New button. It will trigger the opening of the Legal entity creation dialogue.</p> <p>The Importer is created and simultaneously linked to the Substance or Mixture dataset. To complete the information of this newly created Legal entity, click the Goto</p>	Entity reference field	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries. LegalEntity

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	<p>button. The modifications will be automatically updated by clicking the Save button . The Back button button will lead back to section 1.7 Suppliers. The link can be deleted by clicking the Delete button .</p>		
Agreement	<p>Insert the agreement document. Click the Attachment button and the green Plus button from the context menu appearing. Specify the path and the name of the file to be inserted and indicate any remarks if appropriate in the Properties window.</p>	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentati onInfo.ImporterEntries. Agreement
Other importers			

1.2.1 Location of manufacturing plant(s)

Purpose

Provide the name and address of each manufacturing plant in which the plant protection product and active substance are manufactured.

FLEXIBLE_RECORD.Sites – v.4.0 (Final) [July 2020]			
Name	Instructions	Data Type	Field Path
	<p>Set the confidentiality and regulatory purpose flags. The flag system can be used in case of joint submission of information or if there is more than one manufacturer of the same substance and certain infrastructure/facilities are shared.</p>	Confidentiality	FLEXIBLE_RECORD.Site s.DataProtection

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	<p>Caution The flags are set for all sites altogether. There is no possibility to filter out only one Legal entity site from an export file, a print-out or a Dossier.</p> <p>Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants</p>		
Site	<p>Click the green Plus button to open a new repeatable block. An empty block is now ready to be filled in. Add as many repeatable blocks as necessary to list all production and/or /use locations.</p> <p>Site: Click the Link button to select the Site and establish the link. If the desired Site is not present in your database, click the New button. It will trigger the opening of the Legal entity site creation dialogue. The Legal entity site is created and simultaneously linked to the Substance or Mixture dataset. To complete the information of this newly created Site, click the Goto button. The modifications will be automatically updated by clicking the</p>	Entity reference field	FLEXIBLE_RECORD.Site s.ReferenceSite

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	<p>Save button . The Back button will lead back to section 3.3 Sites. The link can be deleted by clicking the Delete button .</p> <p>Caution</p> <p>To delete only the link to the Site information click the Delete button located near the Site field. To delete all information on the Site, click the Delete button located at repeatable block level.</p>		
Remark	A remark field to enter additional information on the Site.	Text area	FLEXIBLE_RECORD.Site.s.Remarks
Manufacture / own use(s)		Header 1	FLEXIBLE_RECORD.Site.s.Manufacture
Related manufacture / own use	<p>Click the Linkbutton to select the relates manufacture / own use and establish the link to the Site.</p> <p>Note</p> <p>In case of a Distributor only, no manufacture / own use should be linked to the Site.</p>	Endpoint reference list	FLEXIBLE_RECORD.Site.s.Manufacture.RelatedManufacture
Related mixture/product		Header 1	FLEXIBLE_RECORD.Site.s.RelatedMixtureProduct
Specify to which mixture/product(s) it applies:		Endpoint reference list	FLEXIBLE_RECORD.Site.s.RelatedMixtureProduct.SpecifyToWhichMixtureProductItApplies

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1.5 Producer's development code numbers

Purpose:

Development code numbers of the preparation referred to in the dossier as well as the current names and numbers must be provided.

Full detail of any differences must be provided.

Completion of this document is optional for EU_PPP

FLEXIBLE_RECORD.Identifiers – v.2.3 (Final) [July 2020]			
Name	Instructions	Data Type	Field Path
Regulatory programme identifiers		Header 1	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers
Regulatory programme identifiers			FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers
Flags	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.DataProtection
Regulatory programme	Select one identifier type from the drop-down list. . If none of the pre-defined items applies, select other:. A text field is then activated next to the list field in which you can enter any free text.	Open list	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgramme
ID	Not relevant for EU-PPP Insert the identification number distributed by different regulatory programmes (e.g. the REACH registration number).	Text	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.Id
Remarks	If necessary, provide any additional comments here.	Text area	FLEXIBLE_RECORD.Identifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers

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			toryProgrammeIdentifiers.Remarks
Regulatory programme identifiers			
Other IT system identifiers		Header 1	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers
Other IT system identifiers			FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers
Flags	Set the confidentiality/regulatory purpose information.	Confidentiality	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers.DataProtection
IT system	Specify the IT System identifier (e.g. IUCLID 4)	Text	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers.ExternalSystemDesignator
ID	Insert the corresponding identification number.	Text	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers.Id
Remarks	If necessary, provide any additional comments here.	Text area	FLEXIBLE_RECORD.Identifiers.ExternalSystemIdentifiers.ExternalSystemIdentifiers.Remarks
Other IT system identifiers			

1.8 Method of manufacture (synthesis pathway) of the active substance

<p>Purpose: To describe the method of manufacture (synthesis pathway) of the active substance. For each manufacture plant, describe, the purity of the starting materials, chemical pathways involved and identity of impurities present in the final product.</p>

FLEXIBLE_RECORD.Manufacturer_EU_PPP – v.1.1 (Final) [October 2020]			
Name	Instructions	Type	Field Path
Administrative data		Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.Ad

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			ministrativeDataSummary
	<p>See Confidentiality of dossiers</p> <p>Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants</p>	Confidentiality	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary.DataProtection
Related compositions	<p>Link to one or more compositions of the substance can be made which will then display the corresponding name(s). This link enables to transparently identify which composition of the substance is relevant for which use during its life cycle (from manufacture to service life).</p>	Endpoint reference list	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary.RelatedCompositions
Description of key information	<p>Describe the manufacturing process e.g. chemical pathways involved.</p> <p>Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilised. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale</p>	Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.Key Information

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	production are not available, a justification shall be provided.		
	This text will be published.	Rich text area	FLEXIBLE_RECORD.Manufacturer_EU_PPP.KeyInformation.field4764
Additional information	State the manufacturing plant if separate documents are provided for each manufacturing plant	Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation
	This text will be published.	Rich text area	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.field7821
Grounds for confidential file	<p>Select one or more of the following grounds for confidentiality to justify the claim</p> <p>Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of Regulation (EC) No 178/2002)</p> <p>the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety; commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;</p>	Multi select open list with remarks	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.GroundsForConfidentialFile

	<p>commercial information revealing sourcing, market shares or business strategy of the applicant</p> <p>quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety</p> <p>Article 63(2)(b) of Regulation (EC) No 1107/2009</p> <p>the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities</p> <p>Article 63(2)(c) of Regulation (EC) No 1107/2009</p> <p>results of production batches of the active substance including impurities</p>		
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	<p>Article 63(2)(d) of Regulation (EC) No 1107/2009</p> <p>information on the complete composition of a plant protection product</p> <p>Article 39e (2) of Regulation (EC) No 178/2002</p> <p>except for personal data (names and addresses) of individuals involved in testing on vertebrate studies or in obtaining toxicological information</p>		
Justification	Provide additional information to support the claim	Text area	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.Justification
Conditions	<p>Select condition/s that apply to the confidentiality claim</p> <p>Public availability: the document, information or data for which confidentiality status is requested is not publicly available or is known only to a limited number of persons;</p> <p>Potential harm: the public disclosure of the document, information or data for which confidentiality status is requested may</p>	Multi select open list with remarks	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.Conditions

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	<p>potentially harm the interests of the applicant to a significant degree and that the harm that may be caused is of a significance corresponding at least to 5% of their total gross turnover for legal persons, or earnings for natural persons, in the year preceding that of the submission of the confidentiality request. If the harm is quantified as not reaching this percentage, or the applicant is unable to calculate its impact on their turnover/earnings, the applicant should provide a specific reason in the form of a free text in the respective Justification box on why they considered that any public disclosure would potentially harm their interests to a significant degree.</p> <p>Worthiness of legal protection: the document, information or data for which confidentiality treatment is requested is eligible for legal protection in the form</p>		
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	<p>of the award of the confidentiality status.</p> <p>Environmental Protection: the document, information or data for which confidentiality status is requested does not fall under the definition of “environmental information” pursuant to Article 2 of the Aarhus Regulation.</p> <p>Novelty: the document, information or data for which confidentiality status is requested has not been finalised in the form submitted to EFSA more than five years prior to the submission of the confidentiality request. If the document, information or data deemed to be awarded confidential status is older than five years, the applicant shall provide a specific reason in the form of a free text in the respective Justification on why public disclosure of that information would still potentially harm its interests to a significant degree.</p>		
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<p>Document J</p>	<p>Document J can be uploaded here, this file will not be published. The filled-in "IUCLID templates for PPP Risk Assessment - Template 1.1 - Template for presentation the assessment for the equivalence of batches" (https://doi.org/10.5281/zenodo.4557366) shall be included in Document J. The relevant IUCLID documents should be completed. However Document J can contain the information previously included in this document to ensure a complete assessment for an interim period until all sections are available in the 'Working contexts' with appropriate confidentiality management.</p> <p>For this reason analytical methods for impurities which are not toxicologically relevant should be reported in Doc J.</p>	<p>Single file attachment</p>	<p>FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.DocumentJ</p>
<p>Sanitised Document J</p>	<p>If relevant, a sanitised version can be uploaded.</p>	<p>Single file attachment</p>	<p>FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.SanitisedDocumentJ</p>
<p>Attached background material</p>	<p>Additional background material can be uploaded here, use remarks to indicate the contents of the uploaded files</p>		<p>FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedBackgroundMaterial</p>

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Attached document	Upload supporting material (e.g. Excel files) as described in regulatory guidance. Click the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document.	Single file attachment	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A sanitised version of any submitted background material must be uploaded here, these will be published	Attachments list	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedSanitisedDocsForPublication

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1.9 Specification of purity of the active substance in g/kg

Purpose

The minimum content in g/kg of pure active substance in the manufactured material used for production of plant protection products, shall be reported. A justification shall be provided for the minimum content proposed in the specification; this shall include a statistical analysis of the data on at least five representative batches, as referred to in point 1.11. Additional supporting data may be provided to further justify the technical specification.

Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilized. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.

For microorganisms; the identity and maximum content of all contaminating micro-organisms, expressed in the appropriate unit, must be reported, where relevant detailed information on all components such as condensates, culture medium, etc. must be provided, identity and content should also be reported for impurities and additives

If the active substance is manufactured as technical concentrate (TK), the minimum and maximum content of the pure active substance shall be given, along with its content in the theoretical dry weight material.

If the active substance is a mixture of isomers, the ratio or the ratio range of the content of isomers shall be provided. The relative biological activity of each isomer, both in terms of efficacy and toxicity, shall be reported.

For plant extracts, a different approach may be taken if adequately justified.

FLEXIBLE_RECORD.SubstanceComposition v.7.4 (Final)			
Name	Instructions	Data type	Field path
General Information	To report the analytical profile of batches a substance composition document should be completed for each batch	Header 1	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation
Name	Indicate a name representative of the composition.	Text	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.Name
Type of composition	Select the type of composition as appropriate. - A 'legal entity composition of the substance refers to a composition specific to the party carrying out the application/notification/registration.	Open list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.TypeOfComposition
State / form	Indicate the physical state and form of the composition. The picklist is not exhaustive, but aims to reflect states and forms that may influence the properties of the substance. If none of pre-defined picklist items appropriately describe your composition, select 'other:'. A text field is	Open list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.StateForm

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	then activated next to the list field in which you can enter the state and form of the composition. If multiple options apply, please create a separate composition for each.		
Description	Include in this field, as appropriate, additional information on the composition. For a complex substance, the description should enable the understanding of the process that led to the particular composition. Free-text templates are available to support the user in providing a suitable description.	Text template	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.DescriptionOfComposition
Justification for deviations	Provide in this field, if relevant, the justification for deviating from agreed conventions when reporting the composition. Such deviations can for example relate to the definitions of substance types (e.g. mono-constituent substance), or the level to which a composition has been described in terms of separate constituents, impurities and additives. Consult any programme-specific guidance on how to use this field.	Text area	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.JustificationForDeviations
Attached description / justification	Attach in this table supporting information to describe the composition, e.g. schematics for relevant chemical reactions or process steps that take place in the generation of the composition.		FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription
Attached document	Upload a file by clicking the upload icon. Documents with confidential material should not be uploaded in this field.	Single file attachment	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.AttachedDocument
Remarks	Provide information about the contents of the attached document.	Text	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.Remarks
Attached description / justification			
Related composition(s)		Header 2	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.RelatedCompositions
Related composition	Use this field, where relevant, to link compositions of the type 'legal entity composition of the substance' to other compositions in the same dataset.	Endpoint reference	FLEXIBLE_RECORD.SubstanceComposition.GeneralInf

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	Typically, this field is used to link a legal entity composition to the boundary composition that encompasses that legal entity composition. The field is active only for compositions of the type 'legal entity composition of the substance' to prevent multiple links between the same compositions. Related compositions in other datasets or dossiers should be referred to textually in the field 'Reference to related composition(s)'.	nce list	ormation.RelatedCompositions.RelatedComposition
Reference to related composition(s)	Use this field, where relevant, to refer compositions of the type 'legal entity composition of the substance' to compositions in other datasets. Typically, this field is used to provide a textual reference from a legal entity composition to the boundary composition that encompasses the legal entity composition, when the boundary composition is provided in another dataset. The field is active only for compositions of the type 'legal entity composition of the substance' to prevent multiple referencing between the same compositions. Related compositions located in the same dataset should be linked in the field 'Related composition'.	Multi-line text	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.RelatedCompositions.ReferenceToRelatedCompositions
Degree of purity		Header 1	FLEXIBLE_RECORD.SubstanceComposition.DegreeOfPurity
	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.DegreeOfPurity.DataProtection
	Indicate the degree of purity; give the purity with the upper and lower limit for typical commercial batches of the substance. For providing only a single numeric value; enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.DegreeOfPurity.Purity
Constituents	This part is a repeatable block subsection enabling to provide detail on all constituents of a specific composition of the substance. Click the Plus button to open the repeatable block. If the composition contains more than one constituent, add a new block to describe each constituent.	Header 1	FLEXIBLE_RECORD.SubstanceComposition.Constituents
			FLEXIBLE_RECORD.SubstanceComp

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			osition.Constituents.Constituents
	Set confidentiality and regulatory programme flags. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.DataProtection
Reference substance	Assign here the reference substance that identifies the constituent. Click the Arrow button to access a linked reference substance and modify it as appropriate. Click the Link button to link/change the reference substance. If the desired reference substance is not present in your database, click the New button at the bottom of the Query window and insert the information of the reference substance in the available fields. For further information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window. Where relevant detailed information on all components such as condensates, culture medium, etc. must be provided	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.ReferenceSubstance
Typical concentration	Indicate the typical concentration of the constituent in the selected composition of the substance. Note: scientific notation can be used, 5e7= 500000000\ For technical specifications this field must be completed	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.ProportionTypical
Concentration range	Indicate the concentration range of the constituent the selected composition of the substance. If only providing a single numeric value: -Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.Concentration
Remarks	Provide additional information about the constituent, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.Remarks

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Impurities	This part is a repeatable block subsection enabling to provide detail on all impurities of a specific composition of the substance. Click the Plus button to open the repeatable block. If the composition contains more than one impurity, add a new block to describe each impurity.	Header 1	FLEXIBLE_RECORD.SubstanceComposition.Impurities
			FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities
	Set confidentiality and regulatory programme flags. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.DataProtection
Reference substance	Assign here the reference substance that identifies the impurity. Click the Arrow button to access a linked reference substance and modify it as appropriate. Click the Link button to link/change the reference substance. If the desired reference substance is not present in your database, click the New button at the bottom of the Query window and insert the information of the reference substance in the available fields. For further information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window.	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.ReferenceSubstance
Typical concentration	Indicate the typical concentration of the impurity in the selected composition of the substance. Ensure to follow regulatory guidance on what constitutes an impurity. For technical specifications this field must be completed	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.ProportionTypical
Concentration range	Indicate the concentration range of the impurity the selected composition of the substance. If only providing a single numeric value: -Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.Concentration
Remarks	Provide additional information about the impurity, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.Remarks

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This impurity is considered relevant for the classification and labelling of the substance	Select the checkbox to indicate that the impurity has an impact on the classification and labelling of the substance.	Check box	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.RelevantForClassificationLabeling
Additives	This part is a repeatable block subsection enabling to provide detail on all additives of a specific composition of the substance. Click the Plus button <image> to open the repeatable block. If the composition contains more than one additive, add a new block to describe each additive.	Header 1	FLEXIBLE_RECORD.SubstanceComposition.Additives
			FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives
	Set confidentiality and regulatory programme flags. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.DataProtection
Reference substance	Assign here the reference substance that identifies the additive. Click the Arrow button to access a linked reference substance and modify it as appropriate. Click the Link button to link/change the reference substance. If the desired reference substance is not present in your database, click the New button at the bottom of the Query window and insert the information of the reference substance in the available fields. For further information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window.	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.ReferenceSubstance
Typical concentration	Indicate the typical concentration of the additive in the selected composition of the substance. For technical specifications this field must be completed	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.ProportionTypical
Concentration range	Indicate the concentration range of the additive the selected composition of the substance. If only providing a single numeric value:	Range with	FLEXIBLE_RECORD.SubstanceComposition.Additives.A

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	-Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	open list (Decimal)	dditives.Concentration
Function	Indicate the function of the additive in the composition of the substance. Ensure to follow regulatory guidance on what constitutes an additive.	Open list	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.Function
Details of function in composition	Provide further information related to the function of the additive in the composition of the substance. In particular, if selecting a less specific entry in the previous 'Function' field, it is recommended to include more details on the function in this field.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.DetailsOfFunctionInComposition
Remarks	Provide additional information about the additive, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.Remarks
This additive is considered relevant for the classification and labelling of the substance	Select the checkbox to indicate that the additive has an impact on the classification and labelling of the substance.	Check box	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.RelevantForClassificationLabelling
Characterisation of nanoforms	This section is not relevant for pesticides	Header 1	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms
Characterisation of polymers	This section is not relevant for pesticides	Header 1	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers

2. Physical, chemical and technical properties of the active substance - Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details for:

- Appearance
- Flammability (state purity)
- Explosive properties (state purity)
- Oxidizing properties (state purity)

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ENDPOINT_SUMMARY.PhysicalChemicalProperties – v.5.0 (Final) [July 2020]			
Name	Instructions	Data Type	Field Path
Administrative data	See Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.PhysicalChemicalProperties.AdministrativeDataSummary
Additional information	See Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.PhysicalChemicalProperties.Discussion

2.1 Melting point and boiling point

2.1.1 Melting point – Endpoint summary

Purpose:

Summary information of the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:

- melting point values in (°C) and their mean for each set of test conditions and the overall mean
- rate of temperature increase if available
- decomposition or sublimation temperature (if applicable)
- if testing is waived, the reasons for waiving must be documented
- the freezing or solidification point instead of the melting point, if it is more appropriate
- the pure point, in case none of the other parameters can be conveniently measured due to particular properties of the substance

The document should contain the information needed to be reported according to the list of end points for melting point (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.Melting v5.0 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.Melting.AdministrativeDataSummary

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Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Melting.KeyValueForChemicalSafetyAssessment
Melting / freezing point at 101 325 Pa		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Melting.KeyValueForChemicalSafetyAssessment.MeltingFreezingPoint
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Melting.Discussion

2.1.1 Melting point – Endpoint study record

Purpose:

The melting point or where appropriate the freezing or solidification point of purified active substance shall be determined and reported. Measurements shall be taken up to 360 °C. Where melting point or boiling point cannot be determined because of decomposition or sublimation, the temperature at which decomposition or sublimation occurs shall be reported.

All information and remarks relevant for the interpretation of results have to be reported, especially with regard to impurities and physical state of the substance.

Beside the measured values (°C) an estimation of the accuracy, measurement uncertainty, is to report. Any deviation from the guideline method used or any other special consideration should be reported.

ENDPOINT_STUDY_RECORD.Melting v7.3 (Final) [May 2021]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Melting.AdministrativeData

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	Description of key information field: The short description should include for example: the test material purity.		
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Melting.DataSource
Materials and methods	Material and methods – common block Applicable Test guideline: Method A.1 Melting/Freezing temperature (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 102: Melting Point/ Melting Range	Header 1	ENDPOINT_STUDY_RECORD.Melting.MaterialsAndMethods
Test material	Test material – common block In test material information: As a minimum, the purity, chemical name, identifier and/or CAS number and molecular weight must be provided	Header 2	ENDPOINT_STUDY_RECORD.Melting.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block In this field you should include the purity of the test material purity and specification	Header 2	ENDPOINT_STUDY_RECORD.Melting.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsIncludeTables

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Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion
Melting / freezing point	Enter mean value of melting/freezing point or range if reported so, together with data on atmospheric pressure, decomposition and sublimation as applicable. For comparison reason, temperature data should be recorded in degrees Celsius (°C). If reported in degrees Fahrenheit (°F), it is recommended to convert to °C. Likewise, pressure data should be given in hPa. By copying this block of fields both the original and converted value(s) can be entered.		ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.MeltingPoint
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.MeltingPoint.KeyResult
Melting / freezing pt.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<'	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.MeltingPoint.MeltingPoint

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	or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
Atm. press.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.MeltingPoint.Pressure
Decomposition	Indicate whether decomposition occurs. Any remarks can be entered in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.MeltingPoint.DecompIndicator
Decomp. temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.MeltingPoint.DecompTemp
Sublimation	Indicate whether decomposition occurs. Any remarks can be entered in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.MeltingPoint.SublimationIndicator

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Subl. temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.MeltingPoint.SublimationTemp
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.MeltingPoint.RemarksOnResults
Melting / freezing point			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Melting.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Melting.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Melting.ApplicantSummaryAndConclusion

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2.1.2 Boiling point – Endpoint summary

Purpose:

Summary information of the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:

- boiling point values in (°C)
- method used
- purity of test material
- pressure value and unit
- rate of temperature increase if available
- decomposition (if applicable)
- if testing is waived, the reasons for waiving must be documented

The document should contain the information needed to be reported according to the list of end points for boiling point (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.BoilingPoint v5.0 (Final)

Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BoilingPoint.AdministrativeDataSummary
Description of key information	<p>Enter a short description of the most relevant endpoint data. The short description could include for example:</p> <ul style="list-style-type: none"> -the test guideline used, -test material purity, -the test organism, -the exposure duration, -the contextual information of the origin of the value, -qualitative characterisation of some properties <p>Examples:</p> <ul style="list-style-type: none"> -“Melting point: 54.6-55.8 °C at 1,013 hPa Purity: 99.8% (EEC Guideline A.1: 	Header 1	ENDPOINT_SUMMARY.BoilingPoint.KeyInformation

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	Thermal analyses (Differential scanning calorimetry (DSC))” -“Short term toxicity to fish: LC50 (96h) < 100 mg/l for Pimephales promelas (OECD TG 203, static)”		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.BoilingPoint.KeyValueForChemicalSafetyAssessment
Boiling point at 101 325 Pa		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BoilingPoint.KeyValueForChemicalSafetyAssessment.BoilingPoint
Temperature of decomposition (state purity)		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BoilingPoint.KeyValueForChemicalSafetyAssessment.TemperatureOfDecompositionStatePurity
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - if more than one studies provided please describe the results of these studies and the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake 	Header 1	ENDPOINT_SUMMARY.BoilingPoint.Discussion

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	<p>of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. If there is no additional information to be reported this field may be left empty.</p>		
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2.1.2 Boiling point – Endpoint study record

Purpose:

The boiling point of purified active substance shall be determined and reported. Measurements shall be taken up to 360 °C. Where boiling point cannot be determined because of decomposition or sublimation, the temperature at which decomposition or sublimation occurs shall be reported. Beside the measured values (°C) an estimation of the accuracy and measurement uncertainty if available is to report. Any deviation from the guideline method used or any other special consideration should be reported.

ENDPOINT_STUDY_RECORD.BoilingPoint v6.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD .BoilingPoint.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD .BoilingPoint.DataSource
Materials and methods	Material and methods – common block Applicable Test guideline: Method A.2 Boiling temperature (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 103: Boiling point	Header 1	ENDPOINT_STUDY_RECORD .BoilingPoint.MaterialsAndMethods

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Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD .BoilingPoint.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD .BoilingPoint.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD .BoilingPoint.ResultsAndDiscussion
Boiling point	Enter mean value of boiling point or range if reported so, together with data on atmospheric pressure, decomposition and sublimation as applicable. For comparison reason, temperature data should be recorded in degrees Celsius (°C). If reported in degrees Fahrenheit (°F), it is recommended to convert to °C. Likewise, pressure data should be given in hPa. By copying this block of fields both the the original and converted value(s) can be entered.		ENDPOINT_STUDY_RECORD .BoilingPoint.ResultsAndDiscussion.BoilingPoint
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD	Check box	ENDPOINT_STUDY_RECORD .BoilingPoint.ResultsAndDiscussion.BoilingPoint.KeyResult

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	Programme, Pesticides NAFTA or EU REACH) on how to use this field.		
Boiling pt.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD .BoilingPoint.ResultsAndDiscussion.BoilingPoint.BoilingPoint
Atm. press.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD .BoilingPoint.ResultsAndDiscussion.BoilingPoint.Pressure
Decomposition	Indicate whether decomposition occurs. Any remarks can be entered in in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD .BoilingPoint.ResultsAndDiscussion.BoilingPoint.Decomposition
Decomp. temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD .BoilingPoint.ResultsAndDiscussion.BoilingPoint.DecompositionTemp

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	For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD .BoilingPoint.ResultsAndDiscussion.BoilingPoint.RemarksOnResults
Boiling point			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD .BoilingPoint.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD .BoilingPoint.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD .BoilingPoint.ApplicantSummaryAndConclusion

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2.2 Vapour pressure, volatility

2.2.1 Vapour pressure – Endpoint summary

Purpose:

Summary information of the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:

- the vapour pressure of the purified active substance at 20 °C or 25 °C
- method used
- purity of the test material
- a log p versus 1/T curve
- an estimate of the vapour pressure values at 20 or 25°C (if not measured at these temperatures)
- if testing is waived, the reasons for waiving must be documented
- if a transition (change of state, decomposition) is observed, please report nature of change, the temperature at which change occurs and the vapour pressure at 10°C and 20°C below and above the transition temperature (unless the transition is from solid to gas)

The document should contain the information needed to be reported according to the list of end points for vapour pressure (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.Vapour v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary v.4.0 (Final) – common block	Header 1	ENDPOINT_SUMMARY.Vapour.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Vapour.KeyValueForChemicalSafetyAssessment
Vapour pressure		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Vapour.KeyValueForChemicalSafetyAssessment.VapourPressure
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Vapour.KeyValueForChemicalSafetyAssessment.TemperatureOf
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Vapour.Discussion

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2.2.1 Vapour pressure – Endpoint study record

Purpose:

The vapour pressure of purified active substance at 20 °C or 25 °C shall be determined and reported. Where vapour pressure is less than 10–5 Pa at 20 °C the vapour pressure at 20 °C or 25 °C shall be estimated by a vapour pressure curve with measurements at higher temperatures. The purity of the test material should be reported. In the case of active substances which are solids or liquids, volatility (Henry's law constant) of purified active substance shall be determined or calculated from its water solubility and vapour pressure and be reported (in Pa × m³ × mol⁻¹).

Beside the measured values (Pa) an estimation of the accuracy is to report. Any deviation from the guideline method used or any other special consideration should be reported.

ENDPOINT_STUDY_RECORD.Vapour v.6.3 (Final) [September 2020]			
Name	Instructions	Data Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Vapour.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Vapour.DataSource
Materials and methods	Material and methods – common block Applicable Test guideline: Method A.4 Vapour pressure (Annex to Regulation (EC) No 440/2008) OECD Test Guideline 104: Vapour Pressure	Header 1	ENDPOINT_STUDY_RECORD.Vapour.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Vapour.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Vapour.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion
Vapour pressure	Enter vapour pressure and the corresponding temperature in the respective subfields. For comparison reason, the data should be recorded in Pa. If reported in other units, it is recommended to convert to Pa. Copy this block of fields for each temperature at		ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Vapourpr

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	which a vapour pressure was determined or for indicating estimates of vapour pressure at 20 or 25°C determined in pre-tests as may be required according to specific test guidelines. If so, include a note ('estimate') in subfield 'Remarks on result'. Give any further relevant information in the field 'Any other information on results incl. tables' as appropriate. For a robust study summary, attach a log p vs. 1/T curve.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Vapourpr.KeyResult
Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Closed list	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Vapourpr.TestNo
Temp.	Enter a numeric value and select the unit.	Half-bound ed with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Vapourpr.TempQualifier
Vapour pressure	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Vapourpr.Pressure
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Vapourpr.RemarksOnResults
Vapour pressure			
Vapour pressure at	If relevant for the classification of a gas under pressure, specify the vapour pressure at 50°C.		ENDPOINT_STUDY_RECORD.Vapour.ResultsAnd

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50°C (if relevant for classification of gas under pressure)			Discussion.VapourPressureAt50CIfRelevantForClassificationOfGasUnderPressure
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.VapourPressureAt50CIfRelevantForClassificationOfGasUnderPressure.KeyResult
Vapour pressure	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.VapourPressureAt50CIfRelevantForClassificationOfGasUnderPressure.VapourPressure
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.VapourPressureAt50CIfRelevantForClassificationOfGasUnderPressure.RemarksOnResults
Vapour pressure at 50°C (if relevant for classification of gas under pressure)			
Transition / decomposition	Indicate whether any transition (change of state, decomposition) was observed. If yes, indicate the temperature at which it occurs at atmospheric pressure and the vapour pressure at 10 and 20 °C above/below this temperature (unless the transition is from solid to gas).		ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Transition
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g.	Check box	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Transition.KeyResult

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	OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.		
Transition / decomposition	Indicate whether any transition (change of state, decomposition) was observed. If yes, complete the fields below and indicate the temperature at which it occurs at atmospheric pressure and the vapour pressure at 10 and 20°C above/below this temperature (unless the transition is from solid to gas).	Closed list with remarks	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Transition.Indicator
Transition temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Transition.Temp
Vapour pressure at 10°C below transition temperature	Indicate the vapour pressure at 10 below the transition temperature (unless the transition is from solid to gas).	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Transition.VapourPressureAt10CBelowTransitionTemperature
Vapour pressure at 10°C above transition temperature	Indicate the vapour pressure at 10°C above the transition temperature (unless the transition is from solid to gas).	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Transition.VapPrAt10
Vapour pressure at 20°C below transition temperature	Indicate the vapour pressure at 20°C below the transition temperature (unless the transition is from solid to gas).	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Transition.VapourPressureAt20CBelowTransitionTemperature
Vapour pressure at 20°C above transition temperature	Indicate the vapour pressure at 20 above the transition temperature (unless the transition is from solid to gas).	Unit measure with Open List	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Transition.VapPrAt20

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		(Decimal)	
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.Transition.RemarksOnResults
Transition / decomposition			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Vapour.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Vapour.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Vapour.ApplicantSummaryAndConclusion

2.2.2 Volatility (Henry's Law constant) – Endpoint summary

<p>Purpose: Provide only the most relevant details, which could be:</p> <ul style="list-style-type: none"> - Volatility (Henry's Law constant) in Pa × m³ × mol⁻¹) - applied method - related conditions (e.g. temperature, pressure, pH, a.s. concentration) <p>The document should contain the information needed to be reported according to the list of endpoints for Henry's law constant (SANCO/12592/2012-rev. 2, 22 March 2019).</p>
--

ENDPOINT_SUMMARY.HenrysLawConstant v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary v.4.0 (Final) – common block In 'Description of key information' field: Enter the calculated Henry's law constant and the temperature	Header 1	ENDPOINT_SUMMARY.HenrysLawConstant.AdministrativeDataSummary

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	at which is calculated. Example: Henry's constant, $H = 1.649 \times 10^{-5} \text{ Pa m}^3 \text{ mol}^{-1}$ (calculated based upon the vapour pressure at 20 °C)		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.HenrysLawConstant.KeyValueForChemicalSafetyAssessment
Henry's law constant (H) (in Pa m³/mol)		Decimal	ENDPOINT_SUMMARY.HenrysLawConstant.KeyValueForChemicalSafetyAssessment.HenrysLawConstant
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.HenrysLawConstant.KeyValueForChemicalSafetyAssessment.AtTheTemperatureOf
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.HenrysLawConstant.Discussion

2.2.2 Volatility (Henry's Law constant) – Endpoint study record

Purpose:

In the case of active substances which are solids or liquids, the Henry's law constant of purified active substance shall be determined or calculated, at 20°C or 25°C, from its water solubility and vapour pressure and be reported (in Pa × m³ × mol⁻¹).

ENDPOINT_STUDY_RECORD.HenrysLawConstant v.7.0 (Final) [June 2021]				
Name	Instructions	Data Type	Field Path	Containing Block name
Administrative data	Administrative data – common block Note for 'Endpoint' field: In the case of active substances which are solids or liquids, the Henry's law constant of purified active substance shall be determined or calculated, at 20°C or	Header 1	ENDPOINT_STUDY_RECORD.HenrysLawConstant.AdministrativeData	Administrative data record block

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	25°C, from its water solubility and vapour pressure and be reported (in Pa × m ³ × mol ⁻¹).			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.HenrysLawConstant.DataSource	Data source block (Literature Reference)
Materials and methods	Material and methods – common block Applicable Test guidelines: - experimental methods: 1) dynamic equilibration approach: a) Batch air stripping (bubble column) b) Concurrent flow (wetted wall column) 2) static equilibration approach: a) Single equilibration b) Multiple Equilibration c) EPICS Technique d) Variable Headspace - prediction method: a) Ratio of water solubility to vapour pressure b) Estimation using connectivity indices c) Estimation using group and bond contribution methods.	Header 1	ENDPOINT_STUDY_RECORD.HenrysLawConstant.MaterialsAndMethods	
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.HenrysLawConstant.MaterialsAndMethods.TestMaterials	Test material block
Study design		Header 2	ENDPOINT_STUDY_RECORD.HenrysLawConstant.MaterialsAndMethods.StudyDesign	
Details on methods	Depending on whether 'experimental result' or 'estimated by calculation' is indicated in field 'Test result type' give relevant details on the methods used to either measure or calculate the Henry's Law constant. Indicate the principles of the method (e.g. OSWER Method or 'Bond contribution method') in field 'Method: remarks / justification'.	Text area	ENDPOINT_STUDY_RECORD.HenrysLawConstant.MaterialsAndMethods.StudyDesign.DetailsOnMethods	

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Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.HenrysLawConstant.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables	Any other information on materials and methods incl. tables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.HenrysLawConstant.ResultsAndDiscussion	
Henry's Law constant H	Enter the Henry's Law constant (H) or lower and upper value in case of range. In the respective subfields you may indicate the temperature and pressure at which H was determined. By repeating this block of fields specify both the dimensionless value(s) and the value(s) in the dimensional form as available. Give any further relevant information in the field 'Remarks on result' as appropriate.		ENDPOINT_STUDY_RECORD.HenrysLawConstant.ResultsAndDiscussion.HenrysLawConstantH	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.HenrysLawConstant.ResultsAndDiscussion.HenrysLawConstantH.KeyResult	
H	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.HenrysLawConstant.ResultsAndDiscussion.HenrysLawConstantH.H	
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.HenrysLawConstant.ResultsAndDiscussion.HenrysLawConstantH.Temp	
Atm. press.	Enter numeric value.	Unit measure	ENDPOINT_STUDY_RECORD.HenrysLawConstant.Resu	

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		with Open List (Decimal)	ItsAndDiscussion.HenrysLawConstantH.AtmPressure	
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.HenrysLawConstant.ResultsAndDiscussion.HenrysLawConstantH.RemarksOnResults	
Henry's Law constant H				
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.HenrysLawConstant.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables	Any other information on results incl. tables Block
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.HenrysLawConstant.OverallRemarksAttachments	Overall remarks, attachments block
Applicant's summary and conclusion	Applicant's summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.HenrysLawConstant.ApplicantSummaryAndConclusion	Applicant's summary and conclusion block

2.3 Appearance (physical state, colour) - Endpoint Summary

Purpose

Provide a description of the colour and of the physical state of the plant protection. Provide a description of both the colour, if any, and the physical state of both the active substance as manufactured and purified active substance.

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ENDPOINT_SUMMARY.GeneralInformation – v.7.1 (Final) [July 2020]			
Name	Instructions	Data Type	Field Path
Administrative data	See Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.GeneralInformation.AdministrativeDataSummary
	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.GeneralInformation.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)	Provide here the link to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.	Header 1	ENDPOINT_SUMMARY.GeneralInformation.LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	ENDPOINT_SUMMARY.GeneralInformation.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.GeneralInformation.LinkToRelevantStudyRecord.Results
Description of key information	Provide a description of the colour and of the physical state of the plant protection. Provide a description of both the colour, if any, and the physical state of both the active substance as manufactured and purified active substance. Report the purity and/or the specification of the test material and the guideline and method used	Header 1	ENDPOINT_SUMMARY.GeneralInformation.KeyInformation

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		Rich text area	ENDPOINT_SUMMARY.GeneralInformation.KeyInformation.KeyInformation
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment
Physical state at 20°C and 1013 hPa	Indicate state at room temperature and atmospheric pressure	Closed list	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.PhysicalState
Form		Open list	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.Form
Colour	Indicate colour	Multi select closed list	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.Colour
Colour intensity		Closed list	ENDPOINT_SUMMARY.GeneralInformation.KeyValueForChemicalSafetyAssessment.ColourIntensity
Additional information	See Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.GeneralInformation.Discussion

2.3 Appearance (physical state, colour) - Endpoint study record

<p>Purpose: For active substances provide a description of both the colour, if any, and the physical state of both the active substance as manufactured and purified active substance.</p> <p>For plant protection product provide a description of the colour and of the physical state of the plant protection.</p>
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ENDPOINT_STUDY_RECORD.GeneralInformation – v.6.3 (Final) [September 2020]			
Name	Instructions	Data Type	Field Type
Administrative data	See Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.AdministrativeData

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Materials and methods	See Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.MaterialsAndMethods
Test material	See Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneralInformation.MaterialsAndMethods.TestMaterials
Test material information	See Test material	Entity reference field	ENDPOINT_STUDY_RECORD.GeneralInformation.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	See Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneralInformation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion
Physical state at 20°C and 1013 hPa	Indicate the physical state of the substance at 20°C and 1013 hPa, i.e. gaseous, liquid or solid. In the case of an aerosol (which means aerosol dispenser or aerosol generator), this field can be left empty. However, the type of aerosol dispenser should be reported in the field "Form". Note: The fields on Test Material Information (TMI) should be completed as far as possible even if the information provided is not derived from a study, but taken from non-experimental information. Create	Closed list with remarks	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.SubstancePhysicalState

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	separate records if different physical states need to be reported.		
Form / colour / odour	This repeatable block is for recording the physical form of the substance odour and colour. Odour is not a data requirement under regulation (EC) No 1107/2009, provision of this information is optional. If the substance can have more than one of these properties, copy this block of fields or create additional records as appropriate.		ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock.KeyResult
Form	Select the physical form of the substance from the picklist, e.g. solid: particulate/powder, solid: nanomaterial, solid: compact, liquid: viscous, etc. If necessary, add further free text description in the adjacent text field, e.g. for further characterising a viscous liquid or an aerosol. The form selected should match with the physical state entered in field 'Physical state at 20°C and 1013 hPa'. The picklist provided is not exhaustive. It	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock.Form

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	<p>includes both comprehensive terms (e.g. 'solid: particulate/powder' or 'solid: nanomaterial') and more specific terms which should be used if possible (e.g. 'solid: flakes' or 'solid: nanomaterial, low aspect ratio'). If substances or mixtures contained in aerosol dispensers are addressed within a specific regulatory framework (e.g. related to classification and labelling), indicate the type of aerosol dispenser.</p> <p>Refer to the guidance documents of the relevant regulatory framework as to the use of this or other template(s) for specifying the physical state, form and other properties of the submission substance during reasonably expected use.</p> <p>Please note: The field 'Test material form' provided in section 'Materials and methods' may be exceptionally obsolete for this template because details on the physical state and form are normally derived from non-experimental information, i.e. handbooks, SDS etc.,</p>		
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	or based on a visual inspection of the substance.		
Colour	Describe the colour of the substance at 20°C and 1013 hPa. If other environmental conditions apply, specify them.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock.SubstanceColour
Odour	Select the odour of the substance from picklist, e.g. biting, pungent, etc.	Open list	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock.Odour
Form / colour / odour			
Substance type	Select as appropriate or use 'other:' to describe substance type if not available from picklist.	Open list	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.SubstanceType
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneralInformation.ApplicantSummaryAndConclusion

2.4 Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity – Flexible record

Purpose:

Spectra of the following analytical methods measured with the purified active substance and a table of signal characteristics shall be determined and reported.

Relevant analytical methods are ultraviolet/visible (UV/VIS), infrared (IR), nuclear magnetic resonance (NMR) and mass spectra (MS).

The most relevant details, which should be provided are the spectra, molar extinction at relevant wavelengths (maxima, wavelength range of 290-700 nm).

In the case of active substances which are resolved optical isomers, the optical purity shall be measured and reported.

Where necessary for the identification of the impurities considered to be of toxicological, ecotoxicological or environmental significance, the UV/visible absorption spectra, IR, NMR and MS spectra, shall be determined and reported as well.

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FLEXIBLE_RECORD.AnalyticalInformation v4.5 (Final)			
Name	Instructions	Data type	Field path
Analytical information		Header 1	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation
	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.DataProtection
Methods and results of analysis	Applicable Test guideline: OECD Test Guideline 101: UV-VIS Absorption Spectra	Header 2	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis
Analytical determination			FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDetermination
Purpose of analysis	Indicate the purpose for which the analysis was carried out (identification and/or quantification).	Closed list	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDetermination.PurposeOfAnalysis
Analysis type	Indicate the analysis type(s) for which you provide a description of the method and/or results; or for which you justify the omission of analytical information. Note that the 'Analysis type' picklist is multi-select list; you can address several analysis types in one row of the table. If none of the pre-defined items apply, select 'other:'. A text	Multi select open list	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDetermination.AnalysisType

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	field is then activated next to the list field in which you can specify the analysis type you wish to provide information on.		
Type of information provided	Indicate the type of information provided for the selected analysis types, as appropriate.	Closed list with remarks	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDetermination.TypeOfInformationProvided
Attached methods/results	Attach here, as appropriate, the methods and/or results for the analysis types you indicated.	Single file attachment	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDetermination.AttachedMethodsResults
Rationale for no results	If no methods/results were provided for the selected analysis types, indicate in this field the underlying reason. If none of the pre-defined items apply, select 'other:'. A text field is then activated next to the list field in which you can specify the type of identifier you wish to provide.	Open list	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDetermination.RationaleForNoResults
Justification	If no methods/results were provided for the indicated analysis types, include in this field the justification. For example, if in the field 'Rationale for no results' you selected 'analysis not technically possible', then provide here the explanation for this selection.	Text area	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDetermination.Justification

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Remarks	Please include a table of signal characteristics needed for interpretation and, where relevant, report the molar extinction at relevant wavelengths (ϵ in $L \times \text{mol}^{-1} \times \text{cm}^{-1}$).	Text area	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDetermination.Remarks
Analytical determination			
Optical activity	Indicate whether the substance is optically active.	Closed list	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.OpticalActivity
Analytical determination for nanoforms			FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDeterminationForNanoforms
Parameter	Indicate the parameter for which the analysis was carried out. If none of pre-defined items apply, select 'other:'. A text field is then activated below the list field in which you can enter the appropriate parameter.	Multi select open list	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDeterminationForNanoforms.Parameter
Purpose of analysis	Indicate the purpose for which the analysis was carried out (identification and/or quantification).	Closed list	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDeterminationForNanoforms.PurposeOfAnalysis
Analysis type	Indicate the analysis type(s) for which you provide a description of the method and/or results; or for which you justify the omission of analytical information. Note that the 'Analysis type'	Multi select open list	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDeterminationForNanoforms.AnalysisType

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	picklist is multi-select list; you can address several analysis types in one row of the table. If none of the pre-defined items apply, select 'other:'. A text field is then activated below the list field in which you can specify the analysis type you wish to provide information on.		
Type of information provided	Indicate the type of information provided for the selected analysis types, as appropriate.	Closed list with remarks	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDeterminationForNanoforms.TypeOfInformationProvided
Attached methods/results	Attach here, as appropriate, the methods and/or results for the analysis types you indicated.	Single file attachment	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDeterminationForNanoforms.AttachedMethodsResults
Rationale for no results	If no methods/results were provided for the selected analysis types, indicate in this field the underlying reason. If none of the pre-defined items apply, select 'other:'. A text field is then activated below the list field in which you can specify the type of identifier you wish to provide.	Open list	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDeterminationForNanoforms.RationaleForNoResults
Justification	If no methods/results were provided for the indicated analysis types, include in this field the justification. For example, if in the	Text area	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDeterminationForNanoforms.Justification

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	field 'Rationale for no results' you selected 'analysis not technically possible', then provide here the explanation for this selection.		
Remarks	Provide additional information about the analysis, as relevant.	Text area	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.AnalyticalDeterminationForNanoforms.Remarks
Analytical determination for nanoforms			
Remarks	Provide here further information on the optical activity of the substance.	Text area	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.MethodsAndResultsOfAnalysis.Remarks
Related composition(s)		Header 2	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.RelatedCompositions
Related composition(s)	This field allows you to link the provided analytical information with the related composition(s) in section 1.2. 'Related composition(s)' is a repeatable block section. Click the Add button  to add a new link.	Endpoint reference list	FLEXIBLE_RECORD.AnalyticalInformation.AnalyticalInformation.RelatedCompositions.RelatedCompositions

2.5 Solubility in water – Endpoint summary

Purpose:

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be the structural formula, vapour pressure, dissociation constant and hydrolysis as a function of pH.
(COMMISSION REGULATION (EC) No 440/2008)

ENDPOINT_SUMMARY.WaterSolubility – v.5.0 (Final) [July 2020]

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Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Report Information to support solubility in water for example: <ul style="list-style-type: none"> - the structural formula - vapour pressure - dissociation constant - temperature - purity and pH 	Header 1	ENDPOINT_SUMMARY.Water Solubility.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Water Solubility.KeyValueForChemicalSafetyAssessment
Water solubility	Report solubility in water in mg or g/L	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Water Solubility.KeyValueForChemicalSafetyAssessment.WaterSolubility
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Water Solubility.KeyValueForChemicalSafetyAssessment.TemperatureOf
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. 	Header 1	ENDPOINT_SUMMARY.Water Solubility.Discussion

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	If there is no additional information to be reported this field may be left empty.		
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2.5 Solubility in water – Endpoint study record

<p>Purpose: The water solubility of purified active substances under atmospheric pressure shall be determined and a value reported for 20 °C. These water solubility determinations shall be made in the neutral range (that is to say in distilled water in equilibrium with atmospheric carbon dioxide). If the pKa is between 2 and 12, water solubility shall also be determined in the acidic range (pH 4 to 5) and in the alkaline range (pH 9 to 10). Where the stability of the active substance in aqueous media is such that water solubility cannot be determined, a justification based on test data shall be provided. (COMMISSION REGULATION (EU) No 283/2013)</p>

ENDPOINT_STUDY_RECORD.WaterSolubility– v.5.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.DataSource
Materials and methods	Material and methods – common block Guideline: OECD 105.	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.StudyDesign
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarks. In the supplementary remarks field, provide method validation. As appropriate attach all relevant chromatograms.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.StudyDesign.AnalyticalMethod

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Details on methods	Provide details on the methods including analytical method, method validation data and all relevant chromatograms (attach as appropriate) particularly if no guideline was used. If the test substance appears 'insoluble' in water, provide the detection limit of the analytical method. Also provide the purity of water used. If an estimation method was used (to be indicated in field 'Test result type') state the equation(s) applied to calculate the water solubility.	Text area	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.StudyDesign.DetailsOnMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion
Water solubility	Enter mean water solubility or range if reported so and indicate the temperature and pH conditions in the respective subfields. If necessary, copy this block of fields for each temperature and pH conditions at which the water solubility was determined. If the pH value was measured with another test substance concentration than the given water solubility concentration, specify the concentration with unit in field 'Details on remarks'.		ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.KeyResult
Water solubility	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.Solubility
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.), or element. As appropriate the measured / addressed fraction can be specified for either of these entities by	Open list with	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion

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	selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	remarks	ssion.WaterSolubility .ConcBasedOn
Loading of aqueous phase	Indicate the loading, i.e. concentration of massive forms and/or powders introduced into the aqueous medium. Select from drop-down list.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.LoadingOfAqueousPhase
Incubation duration	Specify the time until equilibrium was reached in the test.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.IncubationDuration
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.Temp
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.Ph
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.RemarksOnResults
Water solubility			
Solubility of metal	If the concentration of dissolved metal ions in aqueous media was tested in a transformation / dissolution test,		ENDPOINT_STUDY_RECORD.WaterSolub

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Ions in aqueous media	indicate the type of test and the concentrations measured after a distinct incubation period, together with the loading, element analysed and test conditions (temperature, pH and oxygen) in the respective subfields. If necessary, copy this block of fields for different test runs, conditions or several metals released in the case of multi-metallic (e.g. UVCB) substances.		ility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.KeyResult
Type of test	Select from drop-down list.	Open list with remarks	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.TypeOfTest
Mean dissolved conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.MeanDissolvedConc
Element analysed	Specify the element analysed.	Multi-line text	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.ElementAnalysed
Loading of aqueous phase	Indicate the loading, i.e. concentration of massive forms and/or powders introduced into the aqueous medium. Select from drop-down list.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.LoadingOfAqueousPhase
Incubation duration	Specify the duration of incubation for the loading applied. Select from drop-down list.	Unit measure with Closed List	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMed

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		(Decimal)	ia.IncubationDuration
Test conditions	Briefly describe the temperature, pH, oxygen conditions and time interval to determine the concentrations of dissolved metal ions in the water.	Multi-line text	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.TestConditions
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.RemarksOnResults
Solubility of metal ions in aqueous media			
Details on results		Text area	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.ApplicantSummaryAndConclusion

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2.6 Solubility in organic solvents – Endpoint summary

Purpose:

Provide for each organic solvent used the mean or minimum solubility measured, indicate the purity or specification of the active substance, the guideline/ method used and the test temperature. The document should contain the information needed to be reported according to the list of endpoints for solubility in organic solvents (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.SolubilityOrganic v5.0 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.SolubilityOrganic.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.SolubilityOrganic.KeyValueForChemicalSafetyAssessment
Solubility in mg/100g standard fat		Decimal	ENDPOINT_SUMMARY.SolubilityOrganic.KeyValueForChemicalSafetyAssessment.SolubilityStandard
At the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.SolubilityOrganic.KeyValueForChemicalSafetyAssessment.AtTheTemperatureOf
Solubility in organic solvents at 20°C		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.SolubilityOrganic.KeyValueForChemicalSafetyAssessment.SolubilitySolvents
Additional information	Discussion (Header 1) – common block Indicate for each organic solvent used the mean or minimum solubility measured, indicate the purity or specification of the active substance, the guideline/ method used and the test temperature. Provide additional information related to the endpoint, for example: <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment 	Header 1	ENDPOINT_SUMMARY.SolubilityOrganic.Discussion

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	<p>- the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint</p> <p>- the rationale for any user-derived values for the sake of transparency</p> <p>-the possible reasons for differentiating results when several studies were identified to be relevant for the assessment.</p> <p>If there is no additional information to be reported this field may be left empty.</p>		
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2.6 Solubility in organic solvents – Endpoint study record

Purpose:

The solubility of the active substances as manufactured or purified active substance in the following organic solvents at 15 to 25 °C shall be determined and reported if less than 250 g/L; the temperature applied shall be specified. Results shall be reported as g/L.

(a) Aliphatic hydrocarbon: preferably heptane (b) Aromatic hydrocarbon: preferably toluene (c) Halogenated hydrocarbon: preferably dichloromethane

(d) Alcohol: preferably methanol or isopropyl alcohol

(e) Ketone: preferably acetone

(f) Ester: preferably ethyl acetate.

If for a particular active substance, one or more of those solvents is unsuitable (for example reacts with test material), alternative solvents may be used instead. In such cases, choices of solvents shall be justified in terms of their structure and polarity.

ENDPOINT_STUDY_RECORD.SolubilityOrganic v6.3 (Final)

Name	Instructions	Data type	Field path
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Administrative data	Administrative data – common block Note for 'Endpoint' field: Solubility in fat is not a data requirement under commission regulation (EU) No 283/2013.	Header 1	ENDPOINT_STUDY_RECORD.SolubilityOrganic.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SolubilityOrganic.DataSource
Materials and methods	Material and methods – common block Applicable Test guidelines: CIPAC Method MT 181: Solubility in organic solvents CIPAC method MT 157 (water solubility): only in case of a solubility < 10 mg/l	Header 1	ENDPOINT_STUDY_RECORD.SolubilityOrganic.MaterialsAndMethods
Test material	Test material – common block In 'Test material information' field: As a minimum it should be specified if the active substances as manufactured or purified active substance was used and their respective purity and/or specification	Header 2	ENDPOINT_STUDY_RECORD.SolubilityOrganic.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.SolubilityOrganic.MaterialsAndMethods.StudyDesign
Details on methods	Provide details on the methods	Text area	ENDPOINT_STUDY_RECORD.SolubilityOrganic.Mater

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	including analytical method, method validation data and all relevant chromatograms (attach as appropriate) particularly if no guideline was used.		ialsAndMethods.StudyDesign.DetailsOnMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SolubilityOrganic.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SolubilityOrganic.ResultsAndDiscussion
Solubility in organic solvents / fat solubility	Indicate the organic medium used. If necessary, specify the medium in the supplementary remarks field. Enter mean solubility or range if reported so and indicate the temperature in the respective subfield. If necessary, copy this block of fields for each temperature at which the solubility was determined.		ENDPOINT_STUDY_RECORD.SolubilityOrganic.ResultsAndDiscussion.SolubilityOrganic
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SolubilityOrganic.ResultsAndDiscussion.SolubilityOrganic.KeyResult
Medium	Select from drop-down list.	Open list with remarks	ENDPOINT_STUDY_RECORD.SolubilityOrganic.Result

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			tsAndDiscussion.SolubilityOrganic.Medium
Solubility	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.SolubilityOrganic.ResultsAndDiscussion.SolubilityOrganic.Solubility
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.SolubilityOrganic.ResultsAndDiscussion.SolubilityOrganic.Temp
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SolubilityOrganic.ResultsAndDiscussion.SolubilityOrganic.RemarksOnResults
Solubility in organic solvents / fat solubility			
Test substance stable	Indicate whether the test substance was stable under the test	Closed list with remarks	ENDPOINT_STUDY_RECORD.SolubilityOrganic.Result

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	conditions or not. If applicable, include information on the chemical stability in field 'Details on results'.		tsAndDiscussion.TestSubstanceTable
Details on results	Give any further relevant information. For example, a justification for choosing alternative solvents describe any temperature effects if observed and/or polarity-dependent results if different polarities were used. As appropriate include tables with raw data and refer to respective table no. (use predefined table(s) if any or adapt table(s) from study report).	Text template	ENDPOINT_STUDY_RECORD.SolubilityOrganic.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SolubilityOrganic.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.SolubilityOrganic.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SolubilityOrganic.ApplicantSummaryAndConclusion

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2.7 Partition coefficient n-octanol/water– Endpoint summary

Purpose:

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:

- the results of the preliminary estimation
- all information relevant for the interpretation of the results, especially with regard to impurities and physical state of the substance;
- POW values and their mean for each set of test conditions and the overall mean (if there is the suggestion of concentration dependence of the partition coefficient, this should be noted);
- the standard deviation of individual POW values about their mean;
- the overall mean expressed as its logarithm to base 10;
- the theoretical POW when it has been calculated or when the measured value is above 104 .
(OECD Test No. 107: Partition Coefficient (n-octanol/water): Shake Flask Method)

ENDPOINT_SUMMARY.PartitionCoefficient – v.5.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Report Information to support the partition coefficient, for example state: temperature, pH and purity	Header 1	ENDPOINT_SUMMARY.PartitionCoefficient.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.PartitionCoefficient.KeyValueForChemicalSafetyAssessment
Log Kow (Log Pow)		Decimal	ENDPOINT_SUMMARY.PartitionCoefficient.KeyValueForChemicalSafetyAssessment.LowKow
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.PartitionCoefficient.KeyValueForChemicalSafetyAssessment.TemperatureOf
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.PartitionCoefficient.Discussion

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2.7 Partition coefficient n-octanol/water– Endpoint study record

Purpose:

The n-octanol/water partition coefficient (Kow or log Pow) of purified active substance and of all components of the residue definition for risk assessment shall be determined and reported for 20 °C or 25 °C. The effect of pH (4 to 10) shall be investigated when the active substance has a pKa value between 2 and 12.

ENDPOINT_STUDY_RECORD.Partition – v.6.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.DataSource
Materials and methods	Material and methods – common block Guideline: Select the applicable test guideline, e.g. OECD 117 Method A.8 Partition coefficient (Annex to Regulation (EC) No 440/2008). For surface active compounds method A.8 can be applicable if no problems occur (e.g. phase separations). The HPLC method described in Method A.8 is not applicable to surface active compounds.	Header 1	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods
Partition coefficient type	Indicate the type of partition coefficient, normally 'octanol-water'. Select 'other:' and specify as appropriate. Note: Data on the Henry's law constant (air - water	Open list	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.PartitionCoefficientType

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	partition) should be entered in the respective chapter; data on Kd values (e.g., partition / distribution coefficients for soil or sediment) should be recorded in chapters 'Adsorption / desorption' or 'Other distribution data'.		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.StudyDesign
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarks. In the supplementary remarks field, provide method validation. As appropriate attach all relevant chromatograms.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on methods	Provide details on the methods. If an estimation method was used (to be indicated in field 'Test result type') state the equation(s) applied to calculate the value. For experimental studies, use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or	Text template	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.StudyDesign.DetailsOnMethods

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	that are requested by the respective regulatory programme.		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion
Partition coefficient	Enter overall mean partition coefficient or lower and upper value in case of range determined at the temperature and pH conditions indicated in the respective subfields. Copy this block of fields for each temperature and pH conditions at which the partition coefficient was determined or for indicating both Pow and log Pow values.		ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.KeyResult
Type	Indicate if Pow or log Pow is given.	Closed list	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Type
Partition coefficient	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range	Range (Decimal)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Partition

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	use both numeric fields together with the appropriate qualifier(s) if applicable.		
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Temp
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Ph
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.RemarksOnResults
Partition coefficient			
Details on results	Give any further relevant information. As appropriate include table(s) with raw data in the rich text field 'Any other information on results incl. tables'.	Text area	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.DetailsOnResults

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	<p>Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>If requested by the regulatory programme, also attach a chart of relation and fitted regression equation (which includes a correlation coefficient) in field 'Attached background material'.</p>		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.ApplicantSummaryAndConclusion

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2.8 Dissociation in water – Endpoint summary

Purpose:

Summary information of the most relevant study(ies) from which the key value for environmental fate and chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:

- pKa values
- test material purity
- temperature of the test medium (°C)
- type of method used
- if testing is waived, the reasons for waiving must be documented in the dossier.

The document should contain the information needed to be reported according to the list of end points for solubility in organic solvents (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.Dissociation v5.0 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_SUMMARY.Dissociation.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Dissociation.KeyValueForChemicalSafetyAssessment
pKa at 20°C		Decimal	ENDPOINT_SUMMARY.Dissociation.KeyValueForChemicalSafetyAssessment.pka
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Dissociation.Discussion

2.8 Dissociation in water – Endpoint study record

Purpose:

Where dissociation in water occurs, the dissociation constants (pKa values) of the purified active substance shall be determined and reported for 20 °C. The identity of the dissociated species formed, based on theoretical considerations, shall be reported. If the active substance is a salt the pKa value of the non-dissociated form of the active substance shall be given. For substances which contain multiple ionisable functionalities, all measured macro pKa values should be reported and preferably assigned to specific micro-reactions.

In case of substances, which are hydrolytically unstable, readily oxidisable in water, or in cases for which it is not possible to perform any test, the justification of study waiving should be provided.

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ENDPOINT_STUDY_RECORD.DissociationConstant v6.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.DissociationConstant.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.DissociationConstant.DataSource
Materials and methods	<p>Material and methods – common block</p> <p>Applicable Test guidelines: OECD Test Guideline 112: Dissociation Constants in Water.</p> <p>Method A.25 Dissociation constants in water (Annex to Regulation (EC) No 440/2008)</p>	Header 1	ENDPOINT_STUDY_RECORD.DissociationConstant.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.DissociationConstant.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.DissociationConstant.MaterialsAndMethods.StudyDesign
Details on methods	Provide details on the methods including method of calculation, particularly if no guideline was used. If applicable, indicate whether there are multiple acidic and/or basic functional groups. Specify the number and type of functional groups.	Text area	ENDPOINT_STUDY_RECORD.DissociationConstant.MaterialsAndMethods.StudyDesign.DetailsOnMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.DissociationConstant.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

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Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.DissociationConstant.ResultsAndDiscussion
Dissociating properties	Indicate whether the substance has dissociating properties or not.	Closed list with remarks	ENDPOINT_STUDY_RECORD.DissociationConstant.ResultsAndDiscussion.DissociatingProperties
Dissociation constant	If applicable, enter pKa and indicate the temperature in the respective subfield. If only one pKa is given, leave subfield 'No.' empty. If more than one pKa is recorded, copy this block of fields and select consecutive numbers to distinguish each discrete pKa value measured.		ENDPOINT_STUDY_RECORD.DissociationConstant.ResultsAndDiscussion.DissociationConstant
No.	Select a consecutive number from drop-down list if more than one pKa is recorded.	Closed list	ENDPOINT_STUDY_RECORD.DissociationConstant.ResultsAndDiscussion.DissociationConstant.No
pKa	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.DissociationConstant.ResultsAndDiscussion.DissociationConstant.pka
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.DissociationConstant.ResultsAndDiscussion.DissociationConstant.Temp
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.DissociationConstant.ResultsAndDiscussion.DissociationConstant.RemarksOnResults

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	<p>derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.</p>		
Dissociation constant			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.DissociationConstant.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.DissociationConstant.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DissociationConstant.ApplicantSummaryAndConclusion

2.9 Flammability and self heating

2.9.1 Flammability - Endpoint summary

<p>Purpose Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details for flammability (state purity)</p>
--

ENDPOINT_SUMMARY.Flammability – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	<p>Administrative data summary – common block Conclude on the flammability of the product/substance/prep</p>	Header 1	ENDPOINT_SUMMARY.Flammability.AdministrativeDataSummary

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	ation (and state purity)		
Flammability	Indicate 'flammable', 'pyrophoric', 'substances and mixtures which in contact with water emit flammable gases', 'not classified'	Closed list	ENDPOINT_SUMMARY.Flammability.KeyValueChemicalAssessment.Flammability
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Flammability.Discussion

2.9.1 Flammability - Endpoint study record

<p>Purpose</p> <p>Flammability must be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies.</p> <p>“The flammability of active substances as manufactured shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations’ Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria (6). In justified cases, data for purified active substance may be used.”</p> <p>The flammability of solid plant protection products and gases shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations’ Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria.</p>
--

ENDPOINT_STUDY_RECORD.Flammability – v.6.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Flammability.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Flammability.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.Flammability.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Methods A.10 Flammability (solids), A.11 Flammability	Header 1	ENDPOINT_STUDY_RECORD.Flammability.MaterialsAndMethods

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	(gases), A.12 Flammability (contact with water) (Annex to Regulation (EC) No 440/2008) Test N.1: test method for readily combustible solids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/ are relevant for this endpoint		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.Flammability.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.Flammability.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables – (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Flammability.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion
Flammable gases (Lower and upper explosion limit)	Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'. If a gas was tested for flammability, report the		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit

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	<p>lower and upper explosion limit, sometimes also referred to as lower and upper flammability limit. If a calculation method was used fill in the results as far as possible.</p> <p>In field 'Remarks on result' you can indicate if no flammability occurred (no flammable range with air at 20°C and a standard pressure of 101.3 kPa) or if it was not determinable or measured.</p> <p>Copy this block of fields for specifying the relevant values.</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit.Key Result
Parameter	<p>Select the parameter from drop-down list, i.e. lower explosion limit or upper explosion limit.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit.Parameter
Value	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the</p>	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit.Value

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	appropriate qualifier(s) if applicable.		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit.RemarksOnResults
Flammable gases (Lower and upper explosion limit)			
Aerosols	<p>Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'.</p> <p>If an aerosol (which means an aerosol dispenser) was tested for flammability, indicate the type of aerosol tested, the respective test parameter and the result.</p> <p>In field 'Remarks on</p>		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols

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	<p>result' you can indicate for instance if no ignition occurred or if it was not determinable or measured. Copy this block of fields for specifying the relevant values.</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.KeyResult
Type of aerosol tested	<p>Indicate the type of aerosol dispenser tested, i.e. 'aerosol dispenser: foam aerosol' or 'aerosol dispenser: spray aerosol'. Select 'aerosol dispenser: not specified' if the type is not specified. Specific test parameters apply depending on the aerosol type.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.TypeOfAerosolTested
Content of flammable components (%)	<p>Specify the content of flammable components in %. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.ContentOfFlammableComponents
Test parameter	<p>Select the parameter from drop-down list.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.Res

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			ultsAndDiscussion.Aerosols.TestParameter
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.Value
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols.RemarksOnResults
Aerosols			
Flammable solids	Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'.		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids

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	<p>If a solid was tested for flammability, report the test procedure used and the measured burning time.</p> <p>In field 'Remarks on result' you can indicate if no flammability occurred or if it was not determinable or measured.</p> <p>Copy this block of fields for specifying the relevant values.</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids.KeyResult
Test procedure	<p>Select the parameter from drop-down list, i.e. burning rate test: preliminary screening test, burning rate test over 100 mm length, burning rate test with wetted zone, burning time over 250 mm for metal powders or metal alloys.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids.TestProcedure
Burning time	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids.BurningTime

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Moisture (wt %)	Enter a numeric value to specify the moisture as wt %.	Decimal	ENDPOINT_STUDY_RESULTSDiscussion.FlammableSolids.MoistureWt
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RESULTSDiscussion.FlammableSolids.RemarksOnResults
Flammable solids			
Pyrophoric solids	Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'. If a pyrophoric solid was tested for flammability, report the test procedure used and the measured result, i.e. ignition time on contact with air. In field 'Remarks on result' you can indicate if no ignition occurred		ENDPOINT_STUDY_RESULTSDiscussion.PyrophoricSolids

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	or if it was not determinable or measured. Copy this block of fields for specifying the relevant values.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.KeyResult
Test procedure	Select the parameter from drop-down list, i.e. ignition time on contact with air.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.TestProcedure
Result	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.Results
Temp.	Enter a numeric value to specify the air temperature.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.Temp
Relative air humidity (%)	Enter a numeric value to specify the relative air humidity in %.	Decimal	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.RelativeAirHumidity
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived;	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricSolids.RemarksOnResults

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	<ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 		
Pyrophoric solids			
Pyrophoric liquids	<p>Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'.</p> <p>If a pyrophoric liquid was tested for flammability, report the test procedure used and the measured result, i.e. ignition time on contact with air. In field 'Remarks on result' you can indicate if no ignition occurred or if it was not determinable or measured.</p> <p>Copy this block of fields for specifying the relevant values.</p>		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.KeyResult

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	or classification purpose.		
Test procedure	Select the parameter from drop-down list, i.e. ignition time on contact with air or effect on filter paper.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.TestProcedure
Result	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.Results
Temp.	Enter a numeric value to specify the air temperature.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.Temp
Relative air humidity (%)	Enter a numeric value to specify the relative air humidity in %.	Decimal	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.RelativeAirHumidity
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.RemarksOnResults

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Pyrophoric liquids			
Self-heating substances / mixtures	Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'. If a self-heating substance / mixture was tested for oxidative self-heating, report the test procedure used and the result. Copy this block of fields for specifying the relevant values for each test procedure used.		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures.KeyResult
Test procedure	Select the parameter from drop-down list, i.e. 25 mm sample cube at 140°C, 100 mm sample cube at 140°C, 100 mm sample cube at 120°C or 100 mm sample cube at 100°C.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures.TestProcedure
Max. temp. reached	Enter a numeric value to specify the maximum temperature reached.	Decimal	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SelfHeatingSubstancesMixtures.MaxTempReached

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Induction time (h)	Enter a numeric value to specify the induction time.	Decimal	ENDPOINT_STUDY_RESULTSDiscussion.SelfHeatingSubstancesMixtures.InductionTimeH
Result	Report the outcome of test using the test criteria and method of assessing results of the relevant (e.g. UN) test method.	Open list with remarks	ENDPOINT_STUDY_RESULTSDiscussion.SelfHeatingSubstancesMixtures.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RESULTSDiscussion.SelfHeatingSubstancesMixtures.RemarksOnResults
Self-heating substances / mixtures			
Substances / mixtures which in contact with water emit flammable gases	Depending on the information requirement addressed in field 'Endpoint' the respective block of fields should be used for recording study results. Please note that flammable liquids are not covered by this section, but should be recorded in section 'Flash point'. If a substance / mixture		ENDPOINT_STUDY_RESULTSDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases

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	<p>was tested for release of flammable gas, report the test procedure, i.e. step according to the test guideline (i.e. UN Test N.5) and the maximum release rate.</p> <p>In field 'Remarks on result' you can indicate if no ignition occurred or if it was not determinable or measured.</p> <p>Copy this block of fields for specifying the relevant values.</p> <p>In field 'Remarks on result' you can indicate if no ignition occurred or if it was not determinable or measured.</p> <p>Copy this block of fields for specifying the relevant values.</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.KeyResult
Test procedure	<p>Select the step(s) of the test procedure from the multiple drop-down list.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.TestProcedure
Max. rate of gas release	<p>Enter a numeric value to specify the maximum rate of gas release.</p>	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitF

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			flammableGases.MaxRateOfGasRelease
Identity of evolved gas	If gas evolved specify the identity or, if not known, select 'unknown'.	Open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.IdentityOfEvolvedGas
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.RemarksOnResults
Substances / mixtures which in contact with water emit flammable gases			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Flammability.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Flammability.ApplicantSummaryAndConclusion
<p>Links to support material United Nations New York and Geneva (2009) Publication ISBN 978-92-1-139135-0. https://unece.org/DAM/trans/danger/emark/manual/Rev5/English/ST-SG-AC10-11-Rev5-EN.pdf</p>			

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2.9.2 Self-heating - Endpoint summary

<p>Purpose Summary of the most of the relevant study(-ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details e.g. state purity.</p>
--

ENDPOINT_SUMMARY.AutoFlammability – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field Path
Administrative data	Administrative data summary – common block Conclude on the self-heating properties of the product/substance/preparation (and state purity)	Header 1	ENDPOINT_SUMMARY.AutoFlammability.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.AutoFlammability.KeyValueForChemicalSafetyAssessment
Autoflammability / Self-ignition temperature at 101 325 Pa		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.AutoFlammability.KeyValueForChemicalSafetyAssessment.AutoFlammability
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AutoFlammability.Discussion

2.9.2 Self-heating - Endpoint study record

<p>Purpose The self-heating shall be determined and reported, unless it can be justified that it is technically or scientifically not necessary to perform such studies The self-heating of active substances as manufactured shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria. In justified cases, data for purified active substance may be used.</p>
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ENDPOINT_STUDY_RECORD.AutoFlammability – v.6.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path

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Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.AutoFlammability.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Methods A.15 Auto-ignition temperature (liquids and gases), A16 Relative self-ignition temperature for solids, (Annex to Regulation (EC) No 440/2008) Test N.4: test method for self-heating substances (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/ are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AutoFlammability.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.AutoFlammability.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables – (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AutoFlammability.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

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Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion
Auto-ignition temperature (liquids / gases)	Enter the auto-ignition temperature for liquids or gases, i.e. the lowest temperature at which the test substance will ignite in contact with air under the conditions defined in the test method. Also indicate the atmospheric pressure at which it was determined in the respective subfield. If necessary, copy this block of fields for each condition.		ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability.KeyResult
Auto-ignition temperature	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability.Flammability
Atm. Press.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability.AtmosPressure

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	use both numeric fields together with the appropriate qualifier(s) if applicable.		
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with 682emark (2000)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability.RemarksOnResults
Auto-ignition temperature (liquids / gases)			
Relative self-ignition temperature (solids)	Enter the relative self-ignition temperature for solids, i.e. the minimum ambient temperature at which a certain volume of a substance will ignite under defined conditions. If necessary, copy this block of fields for each condition.		ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.RelativeSelfIgnitionTemperatureSolids
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.RelativeSelfIgnitionTemperatureSolids.KeyResult
Relative self-ignition temperature	Enter a single numeric value in the first numeric field if you	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.

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	select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		RelativeSelfIgnitionTemperatureSolids.RelativeSelfIgnitionTemperature
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with 683emark (2000)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.RelativeSelfIgnitionTemperatureSolids.RemarksOnResults
Relative self-ignition temperature (solids)			
Self-ignition temperature of dust accumulation	Enter the self-ignition temperature for a dust, i.e. the lowest temperature, at which under specified test conditions a dust accumulation under the influence of high temperature in the surroundings will just be ignited by self-heating. The self-ignition temperature of a dust accumulation depends on the volume and the shape of the dust sample. Therefore		ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperatureOfDustAccumulation

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	the field 'Volume / surface ratio (m)' should be completed as well. If necessary, copy this block of fields for each condition.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperatureOfDustAccumulation.KeyResult
Self-ignition temperature	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperature
Volume / surface ratio (m)	Enter a numeric value to specify the volume / surface ratio (unit: m).	Decimal	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperatureOfDustAccumulation.VolumeSurfaceRatioM
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks	Open list with 684emark (2000)	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.SelfIgnitionTemperatureOfDustAccumulation.RemarksOnResults

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	field; or - entering any remarks by selecting 'other:'.		
Self-ignition temperature of dust accumulation			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AutoFlammability.ApplicantSummaryAndConclusion

Links to supporting material

United Nations New York and Geneva (2009) Publication ISBN 978-92-1-139135-0.

<https://unece.org/DAM/trans/danger/publi/manual/Rev5/English/ST-SG-AC10-11-Rev5-EN.pdf>

2.10 Flash point – Endpoint summary

Purpose:

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details e.g temperature

ENDPOINT_SUMMARY.FlashPoint v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field Path
Administrative data	Administrative data summary – common block Conclude on the flashpoint of the product/substance/preparation (and state purity)	Header 1	ENDPOINT_SUMMARY.FlashPoint.AdministrativeDataSummary

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Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.FlashPoint.KeyValueForChemicalSafetyAssessment
Flash point at 101 325 Pa	Enter the temperature for flashpoint	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.FlashPoint.KeyValueForChemicalSafetyAssessment.FlashPoint
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.FlashPoint.Discussion

2.10 Flash point – Endpoint study record

Purpose

Flash point must be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

“The flash point of active substances as manufactured with a melting point below 40 °C shall be determined and reported. In justified cases, data for purified active substance may be used.”

The flash point of liquids which contain flammable solvents shall be determined and reported. The flammability of solid plant protection products and gases shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations’ Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria.

ENDPOINT_STUDY_RECORD.FlashPoint – v.7.3 (Final) [September 2020]

Name	Instructions	Data type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.FlashPoint.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Method A.9 Flash-point (Annex to Regulation (EC) No 440/2008) Test methods according to table 2.6.3 of Annex I, Part 2 of Regulation	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods

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	(EC) No 1272/2008 (liquids) are relevant for this endpoint		
Flash point apparatus	Indicate the apparatus used for determining the flash point.	Open list with remarks	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.FlashPointApparatus
Dynamic viscosity of test material	For viscous liquids, report the dynamic viscosity of the test material at 20°C (mPa s) and verify that the method chosen is valid according to the criteria given in the relevant test guideline.	Multi-line text	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.DynamicViscosityOfTestMaterial
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.FlashPoint.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion
Flash point	Enter mean flash point or range if reported so, normally determined at 1013 hPa. If necessary, copy this block of fields for each pressure condition at which the flash point was determined.		ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.FlashPoint
Key result	Set this flag for identifying the key information which is of	Check box	ENDPOINT_STUDY_RECORD.FlashPoint.Result

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	potential relevance for hazard/risk assessment or classification purpose.		sAndDiscussion.FlashPoint.KeyResult
Flash point	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.FlashPoint.Result sAndDiscussion.FlashPoint.FPoint
Atm. press.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.FlashPoint.Result sAndDiscussion.FlashPoint.AtmPressure
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.FlashPoint.Result sAndDiscussion.FlashPoint.RemarksOnResults

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Flash point			
Sustaining combustibility	If a sustaining combustibility test was conducted, specify the test procedure used and report the test result. If necessary, copy this block of fields for test run.		ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.SustainingCombustibility
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.SustainingCombustibility.KeyResult
Test procedure	Specify the test procedure used.	Open list with remarks	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.SustainingCombustibility.TestProcedure
Result	This field can be used for: - giving a qualitative description of results - indicating why no result could be determined, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.SustainingCombustibility.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.SustainingCombustibility.RemarksOnResults

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	by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.		
Sustaining combustibility			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.FlashPoint.ApplicantSummaryAndConclusion

Links to support material

United Nations New York and Geneva (2009) Publication ISBN 978-92-1-139135-0.

<https://unece.org/DAM/trans/danger/publi/manual/Rev5/English/ST-SG-AC10-11-Rev5-EN.pdf>

2.11 Explosive properties – Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.

Provide only the most relevant details e.g explosive properties (state purity)

ENDPOINT_SUMMARY.Explosiveness – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field Path
Administrative data	Administrative data summary – common block Conclude on the explosive properties of the product/substance/prep	Header 1	ENDPOINT_SUMMARY.Explosiveness.AdministrativeDataSummary

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	ration (and state purity)		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Explosiveness.ResultsAndDiscussion
Explosiveness	Select 'explosive', 'non explosive' or no information	Closed list	ENDPOINT_SUMMARY.Explosiveness.ResultsAndDiscussion.Explosiveness
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Explosiveness.Discussion
Justification for classification or non-classification	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Header 1	ENDPOINT_SUMMARY.Explosiveness.Justification

2.11 Explosive properties - Endpoint study record

Purpose

Explosivity properties will be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria

ENDPOINT_STUDY_RECORD.Explosiveness – v.6.4 (Final) [September 2020]

Name	Instructions	Data type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.Explosiveness.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guideline:	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.MaterialsAndMethods

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	Method A.14 Explosive properties (Annex to Regulation (EC) No 440/2008) is relevant for this endpoint		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.Explosiveness.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.Explosiveness.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Explosiveness.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion
Small-scale preliminary tests	If a small-scale preliminary test was conducted (e.g. according to EU Method A.14), report the parameter and results. In field 'Remarks on result' you can indicate any qualitative results or if it was not determinable or measured. Copy this block of fields for specifying the relevant values.		ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.KeyResult

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Parameter	Select the parameter measured to which the result value relates.	Open list with remarks	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.Parameter
Value	Enter a numeric value to specify the result of the test.	Decimal	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.Value
Number of fragments	For thermal sensitivity tests with fragmentation of the test tube, indicate the number of fragments.	Decimal	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.NumberOfFragments
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallScalePreliminaryTests.RemarksOnResults
Small-scale preliminary tests			
Results of test series for explosives	If a substance has explosive properties or is intended to function as explosive, the quantitative and/or qualitative outcome of the relevant tests should be recorded in this repeatable block of fields, as derived according to the test		ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives

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	series indicated in the respective field. In field 'Remarks on result' you can give a qualitative description of results in addition to or if no numeric value(s) were derived. Copy this block of fields for specifying the relevant values.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.KeyResult
Test series	Select the UN test series to which the result value relates. If the test data were derived by a competent authority, select the corresponding phrase.	Open list with remarks	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.TestSeries
Method	Select UN test method to which the result relates.	Open list	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.Method
Parameter	Select the parameter measured to which the result value relates.	Open list with remarks	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.Parameter
Value	Enter a numeric value to specify the result of the test.	Decimal	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.Value
Result	Report the outcome of the test.	Open list with remarks	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.Results

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Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives.RemarksOnResults
Results of test series for explosives			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Explosiveness.ApplicantSummaryAndConclusion

Links to support material:

United Nations New York and Geneva (2009) Publication ISBN 978-92-1-139135-0.

<https://unece.org/DAM/trans/danger/publi/manual/Rev5/English/ST-SG-AC10-11-Rev5-EN.pdf>

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2.12 Surface tension - Endpoint summary

<p>Purpose Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details e.g. Surface tension</p>

ENDPOINT_SUMMARY.SurfaceTension – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block Conclude on the surface tension of the product/substance/preparation (state concentration, temperature and purity)	Header 1	ENDPOINT_SUMMARY.SurfaceTension.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.SurfaceTension.KeyValueForChemicalSafetyAssessment
Surface tension		Decimal	ENDPOINT_SUMMARY.SurfaceTension.KeyValueForChemicalSafetyAssessment.SurfaceTension
in mN/m at 20°C and concentration in mg/L		Decimal	ENDPOINT_SUMMARY.SurfaceTension.KeyValueForChemicalSafetyAssessment.Concentration
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.SurfaceTension.Discussion

2.12 Surface tension - Endpoint study record

<p>Purpose Surface tension will be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies. For liquid formulations the viscosity shall be determined at two shear rates and at 20°C and 40°C and reported together with the test conditions. The surface tension shall be determined at the highest concentration. For liquid plant protection products containing ≥10 % hydrocarbons and for which the kinematic viscosity is less than 7×10^{-6} m²/sec at 40 °C the surface tension of the neat formulation shall be determined at 25 °C and reported.</p>
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ENDPOINT_STUDY_RECORD.SurfaceTension – v.6.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.SurfaceTension.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Method A.5 Surface tension (Annex to Regulation (EC) No 440/2008) OECD Test Guideline 115: Surface tension of aqueous solutions are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Study design		Header 2	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods.StudyDesign
Details on methods	Enter any details that could be relevant for evaluating this study summary. Use freetext template as appropriate.	Text template	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods.StudyDesign.DetailsOnMethods
Any other information on	Any other information on materials and	Header 2	ENDPOINT_STUDY_RECORD.SurfaceTension.

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materials and methods incl. tables	methods incl. tables - (H2) – common block		MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion
Surface tension	Enter mean surface tension or range if reported so and indicate the temperature and test substance concentration in the respective subfields. If necessary, copy this block of fields.		ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension.KeyResult
Surface tension	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension.Tension
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension.Temp
Conc.	Enter numeric value and unit.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.SurfaceTension.Conc
Remarks on result	This field can be used for:	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SurfaceTension.R

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	<ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 		resultsAndDiscussion.SurfaceTension.RemarksOnResults
Surface tension			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SurfaceTension.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.ApplicantSummaryAndConclusion

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2.13 Oxidising properties – Endpoint summary

<p>Purpose Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details for oxidising properties (state purity)</p>			
ENDPOINT_SUMMARY.OxidisingProperties – v.5.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block Conclude on the oxidising properties of the product/substance/preparation (and state purity)	Header 1	ENDPOINT_SUMMARY.OxidisingProperties.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.OxidisingProperties.KeyValueChemicalAssessment
Oxidising properties		Closed list	ENDPOINT_SUMMARY.OxidisingProperties.KeyValueChemicalAssessment.Oxidising
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.OxidisingProperties.Discussion
Justification for classification or non-classification	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Header 1	ENDPOINT_SUMMARY.OxidisingProperties.Justification

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2.13 Oxidising properties – Endpoint study record

<p>Purpose Oxidising properties will be determined, unless it can be justified that it is technically or scientifically not necessary to perform such studies. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria</p>
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ENDPOINT_STUDY_RECORD.OxidisingProperties – v.7.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.OxidisingProperties.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Solids: Method A.17 Oxidising properties (solids) (Annex to Regulation (EC) No 440/2008); Liquids: Method A.21 Oxidising properties (liquids) (Annex to Regulation (EC) No 440/2008); Test O.1: Test for oxidizing solids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/; Test O.2: Test for oxidizing liquids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/; Test O.3: Gravimetric test for oxidising solids (UN)	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods

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	(UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 6; are relevant for this endpoint		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Study design		Header 2	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.StudyDesign
Contact with	Indicate the chemical with which the test substance was brought in contact. Use separate records for each oxidising or reducing agent tested.	Open list	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.StudyDesign.ContactWith
Duration of test (contact time)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.StudyDesign.DurationOfTest
Details on methods	Enter any details that could be relevant for evaluating this study summary, particularly if no guideline was used. For instance, provide the temperature at which the test was	Text area	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.StudyDesign.DetailsOnMethods

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	started and indicate whether the test was conducted at temperatures expected during the normal use of the substance.		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion
Test results (Oxidising gases)	Indicate the type of the parameter measured, i.e. coefficient of oxygen equivalency (Ci), and the numeric results. As appropriate, enter remarks in the respective subfield and/or field 'Remarks on result'. Copy this block of fields for more than one parameter as appropriate.		ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultOxidisingGases
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultOxidisingGases.KeyResult
Parameter	Select the parameter, e.g. coefficient of oxygen equivalency (Ci). Additional free text explanation can be given in the supplementary remarks field.	Open list	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultOxidisingGases.Parameter

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Result	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultOxidisingGases.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultOxidisingGases.RemarksOnResults
Test results (Oxidising gases)			
Test results (Oxidising liquids)	Depending on the method used, indicate the type of sample tested, e.g. 1:1 sample-to-cellulose ratio, and the parameter measured in the respective subfield, e.g. 'mean pressure rise time'. Provide the mean value measured or a range if reported so, and the unit of measurement. As		ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids

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	<p>appropriate, enter remarks in the respective subfield and/or field 'Remarks on result'. Copy this block of fields for more than one parameter as appropriate, i.e. to record the maximum burning rate of both the test mixture and the reference mixture.</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.KeyResult
Sample tested	<p>Select the type of sample tested from drop-down list, e.g. 1:1 sample-to-cellulose ratio. Additional free text explanation can be given in the supplementary remarks field.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.SampleTested
Parameter	<p>Select the parameter, e.g. maximum burning rate. Additional free text explanation can be given in the supplementary remarks field.</p>	Open list	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.Parameter
Result	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the</p>	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.Results

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	appropriate qualifier(s) if applicable.		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids.RemarksOnResults
Test results (Oxidising liquids)			
Test results (Oxidising solids)	<p>Depending on the method used, indicate the type of sample tested, e.g. 1:1 sample-to-cellulose ratio, and the parameter measured in the respective subfield, e.g. 'mean pressure rise time'. Provide the mean value measured or a range if reported so, and the unit of measurement. As appropriate, enter remarks in the respective subfield and/or field 'Remarks on result'.</p> <p>Copy this block of fields for more than one parameter as appropriate, i.e. to record the maximum</p>		ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids

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	burning rate of both the test mixture and the reference mixture.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.KeyResult
Sample tested	Select the type of sample tested from drop-down list, e.g. 1:1 sample-to-cellulose ratio. Additional free text explanation can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.SampleTested
Parameter	Select the parameter, e.g. maximum burning rate. Additional free text explanation can be given in the supplementary remarks field.	Open list	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.Parameter
Result	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids.RemarksOnResults

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	reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.		
Test results (Oxidising solids)			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.ApplicantSummaryAndConclusion

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2.14 Other studies – Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.

Provide only the most relevant details for other physico-chemical properties which cannot be reported in other summaries. This would include adherence and distribution to seeds

ENDPOINT_SUMMARY.AdditionalPhysicoChemical – v.5.0 (Final) [July 2020]

Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.AdditionalPhysicoChemical.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AdditionalPhysicoChemical.Discussion

2.14 Other studies – Endpoint study record

Purpose

This document can be used to summarize studies on any Physical, chemical and technical properties of the plant protection product not covered by the other documents in this section

This document covers the following endpoints

In the case of plant protection products for seed treatment, both distribution and adhesion shall be determined and reported.

In the case of preparations for seed treatment, both distribution and adhesion must be investigated and reported; in the case of distribution in accordance with CIPAC Method MT 175.

ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical – v.6.4 (Final) [September 2020]

Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.DataSource.Reference

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Materials and methods	Material and methods – common block Note: MT 175 - Determination of seed-to-seed uniformity of distribution for liquid seed-treatment formulations MT 83 - Seed adhesion test for powders for seed treatment are relevant for the Adherence and distribution to seeds endpoint	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ResultsAndDiscussion
Results	Report the results of the test(s) performed. Include an interpretation of the results in field 'Conclusions'. Report amount of pesticide detected on seeds after for each condition tested (e.g. shaking or tumbling) or the uniformity of the	Text area	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ResultsAndDiscussion.Results

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	formulation from seed to seed (colormetric measurement)		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ApplicantSummaryAndConclusion
Conclusions	Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any).	Text area	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ApplicantSummaryAndConclusion.Conclusions
Executive summary	If relevant for the respective regulatory programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document.	Rich text area	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ApplicantSummaryAndConclusion.ExecutiveSummary

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3. Further information on the active substance – Endpoint summary

<p>Purpose: This document covers the following endpoints:</p> <ul style="list-style-type: none"> - Function - Effects on harmful organisms / Information of target organisms - Mode of action - Information on (possible) occurrence of resistance development and appropriate management strategies

ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganism - v5.0			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.AdministrativeDataSummary
	Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.AdministrativeDataSummary.DataProtection
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.Discussion

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3.2 Effects on harmful organisms, function, mode of action and possible resistance

3.2 Effects on harmful organisms, function, mode of action and possible resistance

Purpose:

This document covers the following endpoints:

- Function
- Effects on harmful organisms / Information of target organisms
- Mode of action
- Information on (possible) occurrence of resistance development and appropriate management strategies

ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms v.7.3

Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.AdministrativeData
General information		Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation
Background information	Use this field to include any background information, if required, or any relevant introductory remark. Leave field empty if not applicable. Do not include information for which specific fields are provided. PURPOSE OF THIS TEMPLATE: This template can be used for recording general information on the effectiveness of an active substance or a biocidal product, together with its active substances (as required by the relevant legislation). For products, efficacy	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.BackgroundInformation

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	<p>studies should be reported using the corresponding template 'Efficacy data'. For active substances, the effectiveness achieved or claimed should be briefly described in this template. If required or sensible such description can be supported by including summary table(s) which give an overview of relevant efficacy studies performed with a product or products. As appropriate, the general information can be provided in one record or in several individual records. For instance, one record may be sensible if several target organisms, but same function and product type are addressed. Separate records may be sensible for addressing different types of target organisms and functions.</p> <p>Note that this template focuses primarily on biocides. If used for other than this purpose additional pieces of information may have to be added in several fields. Consult the programme-specific guidance on the details to be included.</p>		
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Pest / target organisms to be controlled		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled
Target organisms	Specify the target organism(s) to be controlled. Repeat this block of fields as necessary. Due to the great number of possible target organisms this picklist is not exhaustive. If the species name is not listed, choose an appropriate superior term (e.g. 'Acaridae:') and specify by entering free text in the related field. If organism is not listed at all, choose 'other:' and enter the name or several names in a row in the related text field.		ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms
Scientific name	Select appropriate scientific name from picklist. If not listed, select 'other' and specify. If not given/known, select 'no data'. See also instructions on this block of fields. Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required so according to programme-specific guidance. If so, indicate	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.ScientificName

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	the type of coding system in parentheses.		
Common name	Select appropriate common name from picklist. If not listed, select 'other' and specify. If not given/known, select 'no data'. See also instructions on this block of fields. Any remarks can be entered in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.CommonName
Developmental stage of target pest	Indicate the developmental stage of the target organism. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty. Any remarks can be entered in the supplementary remarks field, for instance any code for the developmental stage if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses.	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.DevelopmentalStage
Developmental stage of target plant	Indicate the developmental stage of the target organism. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.DevelopmentalStageOfTargetPlant
Target organisms			
Products, organisms or objects to be		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.Ge

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protected / under study			neralInformation.ProductsOrganismsOrObjectsToBeProtectedUnderStudy
Organisms (to be protected) or treated materials	Describe and specify the organism(s) or materials(s) / object(s) to be protected, e.g. human, pets, farm animals, fur- and wool-bearing animals, drinking water, hard surface material , porous surface.	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.ProductsOrganismsOrObjectsToBeProtectedUnderStudy.OrganismsToBeProtectedOrTreatedMaterials
Information on intended use and application		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication
Function addressed	Indicate the function of the substance. Multiple selection is possible for indicating additional functions provided they relate to the same product type indicated in the next field. However, it may be sensible or required according to legislation-specific guidance to use separate records for each function. Any remarks can be entered in the supplementary remarks field, for instance any code for the function if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FunctionAddressed
Product type	Indicate the product type in which the active	Open list	ENDPOINT_STUDY_RECORD.EffectivenessAgai

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	<p>substance is intended to be included or which is envisaged for the product. In case of multiple product types use separate records for each of them. Note that only product types related to EU BPD are listed. For other legislations, choose 'other:' and specify in the related text field.</p>		<p>nstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.ProductType</p>
Field of use envisaged / User	<p>If the use conditions are fully described in a GAP document in the dossier, it is sufficient to make reference to the GAP document which describes the use. IUCLID document name and UUID. If this is provided additional information on the use of the product already described in the GAP document does not need to be provided</p>	Text area	<p>ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FieldOfUseEnvisagedUser</p>
Information on application of biocidal product		Header 2	<p>ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfBiocidalProduct</p>
Method of application	See Field of use envisaged / User	Multi select open list with remarks (2000)	<p>ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfBiocidalProduct.MethodOfApplication</p>
Details on application	See Field of use envisaged / User	Text template	<p>ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.Infor</p>

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			mationOnApplicationOf BiocidalProduct.Details OnApplication
General information on effectiveness		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness
Effects on target organisms	<p>The effects on the target organisms required for the claimed efficacy should be described and specified if possible for each use and method of application if these have different effects, including any effect-concentration dependences or the possible existence of a threshold concentration of the active substance. Refer to the instructions given in the relevant guidance documents.</p> <p>In case of a submission of an active substance the effectiveness achieved or claimed should be briefly described. If required or sensible such description can be supported by including summary table(s) which give an overview of relevant efficacy studies performed with a product or products. Upload predefined table(s) in the rich text field 'Overall remarks'. Use table numbers in</p>	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.EffectsOnTargetOrganisms

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	<p>the sequence in which you refer to them in the text (e.g. '... see Table 1'). To show possible differences, the use, i.e. product type and method of application of the biocidal product(s) envisaged should also be given. For products, efficacy studies should be reported using the corresponding template 'Efficacy data'.</p>		
Mode of action	<p>Indicate the principles of the mode of action for the function indicated in above field, e.g. 'acute toxin: contact poison'. If not listed, select 'other' and specify. Any remarks can be entered in the supplementary remarks field, for instance any code for the mode of action if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses..</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ModeAction
Details on mode of action	<p>For the function indicated in above field, indicate the principles of the mode of action; e.g. 'contact poison' or 'stomach poison'. Briefly describe the biochemical and physiological mechanisms, e.g. 'cholinesterase inhibition' and the</p>	Text template	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.DetailsOnModeOfAction

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	biochemical pathway and specify any time delay between application and effect. Use the freetext template as appropriate (delete/add elements). For further instructions refer to the relevant guidance documents		
(Possible) Occurrence of resistance	Indicate whether resistance can possibly develop including cross-resistance. As appropriate include an appraisal of the information gained from the efficacy studies.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.PossibleOccurrenceOfResistance
Management strategies to avoid resistance	Describe any appropriate management strategies towards the minimization of the development of resistance.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ManagementStrategiesToAvoidResistance
Any other known limitations and management strategies	As applicable describe any other known limitations and relevant management strategies towards them.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.AnyOtherKnownLimitationsAndManagementStrategies
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion
Details on results		Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion.DetailsOnResults

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Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ApplicantSummaryAndConclusion

3.3 Methods and precautions concerning handling, storage, transport or fire – Flexible record

<p>Purpose: The risks likely to arise and the methods and procedures to minimize the hazards arising, shall be specified.</p> <ul style="list-style-type: none"> - Recommended methods and precautions. - Emergency measures in the case of an accident, - Procedures for destruction or decontamination - Neutralization procedure - Controlled incineration - Procedures for cleaning application equipment
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FLEXIBLE_RECORD.ProtectionMeasures v.5.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	See Administrative data	Header 1	FLEXIBLE_RECORD.ProtectionMeasures.AdministrativeDataSummary
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.ProtectionMeasures.AdministrativeDataSummary.DataProtection
Instructions for use	Not relevant for pesticides: Instructions for use must be described in the Good	Header 1	FLEXIBLE_RECORD.ProtectionMeasures.InstructionsForUse

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	Agricultural Practice (GAP) document		
Measures to protect humans, animals and the environment		Header 1	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect
Recommended methods and precautions concerning storage of active substance/product; shelf-life of product	<p>Substance: The field is used to identify all methods and precautions concerning the storage of an active substance.</p> <p>Product: The field is used to identify all methods and precautions concerning the storage of a product, including the shelf life of a product. The shelf life of product under normal conditions of storage should be reported.</p>	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.RecommendedMethodsAndPrecautionsConcerningStorage
Recommended methods and precautions concerning handling and transport	<p>Describe all methods and precautions concerning handling and transport.</p> <p>Detailed handling procedures for the storage, at both warehouse and user level of plant protection products must be provided</p> <p>Where appropriate, the nature and characteristics of protective clothing and equipment proposed</p>	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.RecommendedMethodsAndPrecautionsConcerningHandling

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	shall be provided. The data provided shall be sufficient to evaluate the suitability and effectiveness under realistic conditions of use (for example field or glasshouse circumstances)		
Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.	The field is used to identify all methods and precautions concerning fire, and all possible consequences of it. Where available, information on combustion products shall be provided	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.RecommendedMethodsAndPrecautionsConcerningFire
Particulars of likely direct or indirect adverse effects	The field is used to identify all direct or indirect adverse effects.	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.ParticularsOfLikelyDirect
First aid instructions, antidotes	Not relevant for pesticides: Report information on poisoning and treatment in the Medical data document (Section 5.9 Medical data or Section 5.2.6 Direct observation, e.g. clinical cases).	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.FirstAidInstructionsAntidotes
Emergency measures to protect environment in case of accident	Provide information on Emergency measures in the case of an accident and detailed procedures to be followed in the event of an emergency, whether arising during transport, storage or use	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.EmergencyMeasuresToProtectEnvironmentInCaseOfAccident

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	<p>This could include containment of spillages, decontamination of areas, vehicles and buildings, disposal of damaged packaging, absorbents and other materials, protection of emergency workers and residents, including bystanders</p> <p>In the case of micro-organisms, Information on procedures for rendering the micro-organism harmless in the environment (e.g. water or soil) in case of an accident must be provided</p>		
Control measures of repellents or poison included in the product, to prevent action against non-target organisms (relevant for products only)	The field is used to identify all measures that could be taken to prevent action against non-target organisms when using the product.	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.ControlMeasuresOfRepellents
Procedures, if any, for cleaning application equipment (relevant for products only)	The field is used to provide procedures for cleaning the equipment or machinery used for the application of the product. If there is no need to use any additional equipment, please indicate it clearly. Washing and cleaning of protective equipment should also	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.Procedures

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	be described (where relevant). The effectiveness of cleaning procedures shall be described in detail.		
Possibility of destruction or decontamination following release in or on the following:		Header 1	FLEXIBLE_RECORD.ProtectionMeasures.PossibilityOfDestructionOrDecontamination
Air	Describe possibility of destruction or decontamination following release in the air. Release to air is not relevant for microorganisms	Text area	FLEXIBLE_RECORD.ProtectionMeasures.PossibilityOfDestructionOrDecontamination.Air
Water, including drinking water	Describe possibility of destruction or decontamination following release in or on the water, including drinking water.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.PossibilityOfDestructionOrDecontamination.Water
Soil	Describe possibility of destruction or decontamination following release in or on the soil.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.PossibilityOfDestructionOrDecontamination.Soil
Procedures for waste management of active substance/product, and if appropriate, its packaging:	Procedures for destruction and decontamination shall be developed for both small quantities (user level) and large quantities (warehouse level).	Header 1	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement
Possibility of reuse or recycling	Substance: The field is used to identify possibility of reuse or recycling of the active substance and to describe relevant	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.PossibilityOfReuseOrRecycling

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	<p>procedures for industry or professional users.</p> <p>Product: The field is used to identify possibility of reuse or recycling of the product and its packaging and to describe relevant procedures for industry, trained professional, professional users and non-professional users</p> <p>Procedures to preclude or minimise the generation of waste or leftovers shall be provided.</p>		
<p>Neutralisation procedure and possibility of neutralisation of effects</p>	<p>Neutralisation procedures (such as by reaction with other substances to form less toxic compounds) for use in the event of accidental spillages shall be described, where such procedures can be applied</p> <p>Methods to dispose safely of the micro-organism or, where necessary, to kill it prior to disposal, and methods to dispose of contaminated packaging and contaminated materials, must be fully described</p>	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.PossibilityOfNeutralisationOfEffects

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	<p>Substance: The field is used to identify possibility of neutralisation of effects caused by the active substance and to describe relevant procedures for industry or professional users.</p> <p>Product: The field is used to identify possibility of neutralisation of effects caused by the product and its packaging and to describe relevant procedures for industry, trained professional, professional users and non-professional users.</p>		
<p>Conditions for controlled discharge including leachate qualities on disposal</p>	<p>Substance: The field is used to describe conditions for controlled discharge of the active substance, including leachate qualities on disposal. Detailed description of all relevant procedures for industry or professional users should be done.</p> <p>Product: The field is used to describe conditions for controlled discharge of the product, including leachate qualities on disposal. Detailed description of all relevant procedures for industry, trained</p>	<p>Text area</p>	<p>FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.ConditionsForControllerDischarge</p>

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	professional, professional users and non-professional users, should be done.		
Conditions for controlled incineration	<p>If controlled incineration is not the preferred method of disposal, full information on the alternative method of safe disposal used shall be provided (in the other fields in this section)</p> <p>Substance: The field is used to describe conditions for controlled incineration of the active substance. Detailed description of all relevant procedures for industry or professional users should be done.</p> <p>Product: The field is used to describe conditions for controlled incineration of the product. Detailed description of all relevant procedures for industry, trained professional, professional users and non-professional users, should be done.</p>	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.ConditionsForControllerIncineration
Instructions for safe disposal of the product and its packaging for different groups of users (relevant for biocidal products only)	Not relevant for pesticides	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.InstructionsForSafeDisposal

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Additional information		Header 1	FLEXIBLE_RECORD.ProtectionMeasures.AdditionalInformation
Reference	<p>Indicate the bibliographic reference of the study report or publication used to support any or all of the points above. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search. Always enter the primary reference in the first block of fields or sort it to the first position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study.</p> <p>A sanitised version of the report must be</p>	Literature reference list	FLEXIBLE_RECORD.ProtectionMeasures.AdditionalInformation.Reference

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	<p>uploaded in the literature reference for publication, the original version can be included if it differs from the sanitised version</p> <p>Safety datasheets in the form of literature references can be added as references in this field</p>		
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Links to support material:

Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)

<http://data.europa.eu/eli/dir/2010/75/2011-01-06>

4. Analytical methods - Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, which could be: recovery, selectivity (specificity), calibration, precision (repeatability, reproducibility), limit of detection (LOD), and limit of quantitation (LOQ).

([http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)17&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en))

ENDPOINT_SUMMARY.AnalyticalMethods – v.3.0 (Final) [July 2020]

Name	Instructions	Data Type	Field Path
Administrative data	<p>Administrative data summary – common block</p> <p>Description of key information: Provide an assessment of the suitability of the proposed methods for monitoring and enforcement. Note Further information on residue definitions and LOQs can be provided</p>	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.AdministrativeDataSummary

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	in Proposed residue definitions document and Proposed maximum residue levels document in the Residues Section		
Additional information	<p>Discussion (Header 1) – common block Attached (sanitised) documents for publication: The file "Template 4.1 - Template for the overview table for analytical methods for risk assessment" (https://doi.org/10.5281/zenodo.4556992) shall be uploaded here.</p>	Header 1	ENDPOINT_SUMMARY. AnalyticalMethods.Discussion

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Links to support documents

OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39. (ENV/JM/MONO(2007)17)

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)17&oclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&oclanguage=en)

EU guidance document for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99).

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_res_pre-reg-cont-monitor.pdf

EU guidance document on analytical methods for the determination of residues (Post-registration monitoring and control) (SANCO/825/00 rev. 8.1, 2010)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_res_post-reg-cont-monitor.pdf

Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods (SANTE/2017/10632)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_wrkdoc_2017-10632.pdf

4. Analytical Methods - Endpoint study record

Purpose:

The provisions of this Section cover analytical methods used for the generation of pre-approval data and required for post-approval control and monitoring purposes. Descriptions of methods shall be provided and include details of equipment, materials and conditions used. On request, the following shall be provided: (a) analytical standards of the purified active substance; (b) samples of the active substance as manufactured; (c) analytical standards of relevant metabolites and all other components included in all monitoring residue definitions; (d) samples of reference substances for the relevant impurities. Where possible, the standards referred to in points (a) and (c) shall be made commercially available and, on request, the distributing company shall be named.

It is recommended to use the cross-reference feature in endpoint study records to cross link to a specific analytical method endpoint study record used in the study.

ENDPOINT_STUDY_RECORD.AnalyticalMethods – v6.3 (Final) [September 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. DataSource.Reference
Background		Header 1	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. Background
Background information	<p>Use this field to include any background information, if required, or any relevant introductory remarks on the study summary. Leave field empty if not applicable. Do not include information for which specific fields are provided. For instance, include any background information on the test substance in fields on 'Test materials'.</p> <p>PURPOSE OF THIS TEMPLATE: This template can be used for summarising analytical methods for determining a given substance in various matrices. Depending on the requirements of the relevant legislation, methods for the following matrices may have to be recorded: soil, sediment, suspended particulates, air, water (including drinking water), animal and human body fluids and tissues, plants, plant products, food and feedingstuffs, formulated product, other.</p>	Multi-line text	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. Background.Background Information
Materials and methods	<p>Material and methods – common block</p> <p>Guideline: Select the applicable test guideline, e.g. EU guidance document on analytical methods for the analysis of technical material and preparation (SANCO/3030/99 rev. 4)</p> <p>Residues: EU guidance document on analytical methods for the determination of residues (Post-registration monitoring and control) (SANCO/825/00 rev. 8.1, 2010) EU guidance document for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99 rev. 4). OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39.</p>	Header 1	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods
Matrix / medium	Indicate the medium for which the analytical method is described. In the supplementary remarks field, you can	Multi select	ENDPOINT_STUDY_REC ORD.AnalyticalMethods.

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	<p>add explanations as appropriate.</p> <p>Note: The picklist is not descriptive as to whether analytical methods have to be submitted for each of the matrices provided in the picklist. If the methods for several matrices can be summarised in one record, you can copy this field for indicating the respective matrices.</p>	<p>t open list with rema rks</p>	<p>MaterialsAndMethods.M atrixMedium</p>
Test material	<p>Test material – common block</p>	<p>Head er 2</p>	<p>ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.Te stMaterials</p>
Principles of analytical methods		<p>Head er 2</p>	<p>ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.Pri nciplesOfAnalyticalMeth ods</p>
Instrument / detector	<p>Indicate the instrument / detector used for the quantitative analysis including the type of detector, e.g. 'HPLC-UV'. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on analytical data collection method'.</p> <p>Note: If a residue analytical method is recorded, the instrument/detector used for the so-called data collection or data-gathering method should be specified here. Data collection method is the analytical method used to collect quantitative residue data by analysing the analyte(s) in the matrices. This method can be identical with or differ from the so-called enforcement method which has to be recorded under the heading 'Enforcement method (if applicable)'. Enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides.</p>	<p>Multi selec t open list</p>	<p>ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.Pri nciplesOfAnalyticalMeth ods.InstrumentDetector</p>
Details on analytical method	<p>Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product:') in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report.</p> <p>Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the</p>	<p>Text temp late</p>	<p>ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.Pri nciplesOfAnalyticalMeth ods.DetailsOnAnalytical Method</p>

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	terms 'data collection method' and 'enforcement method' see help text for field 'Instrument / detector'. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Enforcement method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable
Instrument / detector for enforcement method	If no enforcement method is proposed or required, ignore this field. An enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides. If such a method is proposed indicate the instrument / detector used in the enforcement method. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on data enforcement method'.	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.InstrumentDetectorForEnforcementMethod
Details on enforcement method	'Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. "parent compound", "parent and transformation products" or "transformation product:") in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report. Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms "data collection method" and "enforcement method" see help text for field "Instrument / detector". Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.DetailsOnEnforcementMethod
Confirmatory method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable

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Instrument / detector for confirmatory method	'If not applicable, ignore this field. If a confirmatory method was used (i.e. applying techniques to demonstrate specificity in case the original method is not highly specific), indicate the instrument / detector used. Note: Not all picklist items may be relevant for a confirmatory technique. Multiple selection is possible if more than one method needs to be specified. Give any further details in field "Details on data confirmatory method".'	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.InstrumentDetectorForConfirmatoryMethod
Details on confirmatory method	Briefly describe further details on the principles of the confirmatory method if any. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Multi-line text	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.DetailsOnConfirmatoryMethod
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion
Recovery results and characteristics of analytical method		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod
Recovery results	Indicate the compound (analyte) addressed (e.g. 'parent compound', 'parent and transformation products' or 'transformation product:'). Report the recovery rates at each level (e.g. at spiking level 1, spiking level 2 etc.) at the limit of quantification and give the mean % recovery and the relative standard deviation in % including the number of recovery studies. Include a brief evaluation of the repeatability of the method (e.g. 'These values demonstrate that the method has satisfactory repeatability.')	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.RecoveryResults

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	Use freetext template and delete/add elements as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Characteristics of analytical method	For each compound (analyte) addressed (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product:'), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio. Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms 'data collection method' and 'enforcement method' see help text for field 'Instrument / detector'. Provide information on extractability studies. Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.CharacteristicsOfAnalyticalMethod
Results using enforcement method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod
Recovery results (enforcement method)	If not applicable, ignore this field. If an enforcement method is proposed which is different from the analytical method described as general analytical method (or 'data-gathering method' in residue analysis), indicate the compound (analyte) addressed (e.g. 'parent compound', 'parent and transformation products' or 'transformation product:'). Report the recovery rates at each level (e.g. at spiking level 1, spiking level 2 etc.) at the limit of quantification and	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.RecoveryResults

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	<p>give the mean % recovery and the relative standard deviation in % including the number of recovery studies. Include a brief evaluation of the repeatability of the method (e.g. 'These values demonstrate that the method has satisfactory repeatability.')</p> <p>Use freetext template and delete/add elements as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>		
Characteristics of enforcement method	<p>If not applicable, ignore this field. If an enforcement method is proposed which is different from the analytical method described as general analytical method (or 'data-gathering method' in residue analysis), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio for each compound (analyte) addressed (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product:').</p> <p>Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.CharacteristicsOfEnforcementMethod
Independent laboratory validation (if applicable)	<p>If not applicable, ignore this field. If applicable (as for enforcement methods), discuss the independent laboratory validation (ILV) in terms of whether or not it was conducted according to guideline specifications. Discuss any method modifications that may impact the analyses of the residues (e.g., altered LOQ) that are suggested by the independent laboratory. Alternatively, include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation

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Independent laboratory validation	If not applicable, ignore this field. If applicable (as for enforcement methods), discuss the independent laboratory validation (ILV) in terms of whether or not it was conducted according to guideline specifications. Discuss any method modifications that may impact the analyses of the residues (e.g., altered LOQ) that are suggested by the independent laboratory. Alternatively, include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation.IndependentLaboratoryValidation
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Further information on extractability can be uploaded in the attachment fields.	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ApplicantSummaryAndConclusion

Links to support material:

OECD GUIDANCE DOCUMENT ON PESTICIDE RESIDUE ANALYTICAL METHODS

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)17&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en)

Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013.

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_3030.pdf

[Guidance document on analytical quality control and method validation procedures for pesticide residues analysis in food and feed](#) - SANTE/12682/2019 - 1 January 2020

[Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods](#) – SANTE 2017/10632 rev.3, 22 November 2017

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5. Toxicological and metabolism studies on the active substance – Flexible summary

Purpose

To report Health-based guidance values than under the pesticides peer review are called toxicological reference values. These are the Acceptable operator exposure level (AOEL), Acceptable daily intake (ADI), Acute reference dose (ARfD) and Acute Acceptable operator Exposure Level (AAOEL) values derived for the active substance or metabolite (if applicable).

FLEXIBLE_SUMMARY.ToxRefValues – v1.1 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	See Confidentiality request Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Header 1	FLEXIBLE_SUMMARY.ToxRefValues.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.ToxRefValues.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	FLEXIBLE_SUMMARY.ToxRefValues.KeyInformation
	Rational for the derivation of the reference values reported below, plus specific information which should be considered when assessing the reported values.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.KeyInformation.KeyInformation
Human health hazard characteristics		Header 1	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics
AOEL (Acceptable operator exposure level)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel

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Not allocated	Check the box if an AOEL is not necessary for the application	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.NoAllocated
Justification	Justification for the non-derivation of an AOEL	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.Justification
AOEL	Report the AOEL value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.Aoel
Study retained	Type of study used to derive the AOEL (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.StudyRetained
Route of original study	Route of exposure in the study used to derive the AOEL	Closed list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.RouteOfOriginalStudy
Oral absorption value (%)	Oral absorption value derived from the toxicokinetic studies expressed as a percentage	Decimal	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.OralAbsorption
Overall uncertainty factor (UF)	<p>The overall assessment factor is the product of all the assessment factors used.</p> <p>The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).</p>	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.OverallUncertainty
Justification of the overall UF	Justification for the uncertainty factor applied considering	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics

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	<p>intra/inter species extrapolation.</p> <p>Please detail if additional UF are applied e.g.:</p> <ul style="list-style-type: none"> - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for AOEL derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. However, by using the BMD approach instead of NOAEL/LOAEL approach there would be not need to apply an additional UF in this case. - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental dose descriptor will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. 		<p>.AcceptableOperatorExposureLevel.Justification OverallUf</p>
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	<p>may be applied to compensate for the potential remaining uncertainties during AAOEL derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used.</p> <p>e.g. In case some studies are missing, additional UF can be added.</p> <p>- UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.</p>		
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.JustificationAndComments
ADI (Acceptable daily intake)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHea

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			lthHazardCharacteristics .AcceptableDailyIntake
Not allocated	Check the box if an ADI is not necessary for the application	Check box	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcceptableDailyIntake. NoAllocated
Justification	Justification for the non-derivation of an ADI	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcceptableDailyIntake. Justification
ADI	Report the ADI value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcceptableDailyIntake. Adi
Study retained	Type of study used to derive the ADI (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcceptableDailyIntake. StudyRetained
Route of original study	Route of exposure in the study used to derive the ADI. It should be by default: oral.	Closed list	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcceptableDailyIntake. RouteOfOriginalStudy
Overall uncertainty factor (UF)	<p>The overall assessment factor is the product of all the assessment factors used.</p> <p>The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).</p> <p>Please detail if additional UF are applied e.g.:</p> <ul style="list-style-type: none"> - UF for dose response relationship i.e. consideration should be given to the 	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcceptableDailyIntake. OverallUncertainty

	<p>uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for AOEL derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10.</p> <ul style="list-style-type: none"> - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental NOAEL will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. may be applied to compensate for the potential remaining uncertainties during AOEL derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative 		
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	<p>data if those have been used.</p> <p>e.g. In case some studies are missing, additional UF can be added.</p> <p>- UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.</p>		
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.JustificationOverallUf
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.JustificationAndComments
ARfD (Acute reference dose)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose
Not allocated	Check the box if an ARfD is not necessary for the application	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics

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			.AcuteReferenceDose.NoAllocated
Justification	Justification for the non-derivation of an ARfD	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.Justification
ARfD	Report the ARfD value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.Arfd
Study retained	Type of study used to derive the ARfD (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.StudyRetained
Route of original study	Route of exposure in the study used to derive the ARfD. It should be by default: oral.	Closed list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.RouteOfOriginalStudy
Overall uncertainty factor (UF)	<p>The overall assessment factor is the product of all the assessment factors used.</p> <p>The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).</p>	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.OverallUncertainty
Justification of the overall UF	Please detail if additional UF are applied e.g.: - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.JustificationOverallUf

	<p>ARfD derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. However, by using the BMD approach instead of NOAEL/LOAEL approach there would be not need to apply an additional UF in this case.</p> <ul style="list-style-type: none"> - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental dose descriptor will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. may be applied to compensate for the potential remaining uncertainties during ARfD derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used. <p>e.g. In case some studies are missing,</p>		
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	<p>additional UF can be added.</p> <p>- UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.</p> <p>Justification for the uncertainty factor applied considering intra/inter species extrapolation</p>		
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.JustificationAndComments
AAOEL (Acute acceptable operator exposure level)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel
Not allocated	<p>Select the box if an AAOEL is not necessary for the application.</p> <p>It should be ticked for each toxicological reference value.</p>	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.NoAllocated

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Justification	Justification for the non-derivation of an AAOEL	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.Justification
AAOEL	Report the AAOEL and if they are available select the relevant units.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.Aaoel
Study retained	Type of study used to derive the AAOEL (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.StudyRetained
Route of original study	Route of exposure in the study used to derive the AAOEL	Closed list	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.RouteOfOriginalStudy
Oral absorption value (%)	Oral absorption value derived from the toxicokinetic studies expressed as a percentage	Decimal	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.OralAbsorption
Overall uncertainty factor (UF)	The overall assessment factor is the product of all the assessment factors used. The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.OverallUncertainty
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation.	Multi-line text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.JustificationOverallUf

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	<p>Please detail if additional UF are applied e.g.:</p> <ul style="list-style-type: none"> - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. <p>For instance, in case the starting point for AAOEL derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. However, by using the BMD approach instead of NOAEL/LOAEL approach there would be not need to apply an additional UF in this case.</p> <ul style="list-style-type: none"> - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental dose descriptor will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. 		
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	<p>- UF for the quality of the whole database i.e. may be applied to compensate for the potential remaining uncertainties during AAOEL derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used.</p> <p>e.g. In case some studies are missing, additional UF can be added.</p> <p>- UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.</p>		
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.field8204
Justification and comments	Provide additional information related to	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHea

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	the derivation of this specific toxicological reference value.		lthHazardCharacteristics.AcuteAcceptableOperationOrExposureLevel.JustificationAndComments
Additional information		Header 1	FLEXIBLE_SUMMARY.ToxRefValues.Discussion
	Provide additional information related to the endpoint, for example: previous Reference Values set for the substance	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.Discussion.Discussion
Attached background material	Upload any additional information related to the derivation of toxicological reference values and provide an indication of the content in the remarks		FLEXIBLE_SUMMARY.ToxRefValues.Discussion.AttachedBackgroundMaterial
Attached document		Single file attachment	FLEXIBLE_SUMMARY.ToxRefValues.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	FLEXIBLE_SUMMARY.ToxRefValues.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	For any attached background material a sanitised version for publication must be provided.	Attachments list	FLEXIBLE_SUMMARY.ToxRefValues.Discussion.AttachedSanitisedDocsForPublication

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Links to support materials:

OECD (2010) "Guidance for the Derivation of an Acute Reference Dose" OECD Series on testing and assessment, No. 124, 08-Jun-2010

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2010\)15&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2010)15&doclanguage=en)

Guidance for the setting of an acute reference dose (ARfD)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_tox_acute-ref-dose.pdf

GUIDANCE FOR THE SETTING AND APPLICATION OF ACCEPTABLE OPERATOR EXPOSURE LEVELS (AOELs)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_tox_accpt-expls-2006.pdf

Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2579>

Update: use of the benchmark dose approach in risk assessment

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4658>

5.1 Studies on absorption, distribution, metabolism and excretion in mammals - Endpoint Summary

Purpose:

Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Absorption, distribution, metabolism and excretion (toxicokinetics):

- Rate and extent of oral absorption/systemic bioavailability
- Toxicokinetics (C_{max}, T_{max}, Plasma T_{1/2})
- Distribution (indicate which organs have the highest levels)
- Rate and extent of excretion
- Provide statement on comparative in vitro metabolism interspecies differences between human and test species.

The document should contain the information needed to be reported according to the list of end points for ADME (SANCO/12592/2012-rev. 2, 22 March 2019).

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

PBPK modelling including results, if available, should be summarised under this section. Modeling codes and results can be uploaded as attachments.

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ENDPOINT_SUMMARY.Toxicokinetics - v5.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	<p>Administrative data summary – common block</p> <p><u>Study name / type:</u> Provide the link to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Currently comparative in vitro metabolism studies should be reported under 5.8 Other toxicological studies (ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation - v.6.3).</p> <p><u>Description of key information:</u> Provide a brief description of toxicity studies and effects. The information provided for absorption, distribution, metabolism and excretion, or observations based on physicochemical properties should be described. The interpretation of the result should be done considering:</p> <ul style="list-style-type: none"> - a discussion on potential data gaps, - the relevance of the results for the risk assessment (e.g. the extent to which the results from an animal 	Header 1	ENDPOINT_SUMMARY.Toxicokinetics.AdministrativeDataSummary

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	study are relevant for human health).		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue
Bioaccumulation potential	This information is usually based on physicochemical properties (e.g. log Kow, molecular structure and molecular weight) and on metabolism. The rationale for the indicated value should be explained in the "Description of key information" field.	Closed list	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.Bioaccumulation
Absorption rate - oral (%)	This information can be obtained experimentally or generated considering physicochemical properties (e.g. water solubility, log Kow, molecular structure, molecular weight)	Decimal	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.AbsorptionOral
Absorption rate - dermal (%)		Decimal	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.AbsorptionDerm
Absorption rate - inhalation (%)	This information can be obtained experimentally or generated considering physicochemical properties (e.g. water solubility, log Kow, molecular structure, molecular weight)	Decimal	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.AbsorptionInhal
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example:	Header 1	ENDPOINT_SUMMARY.Toxicokinetics.Discussion

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	<p>Rate and extent of oral absorption/systemic bioavailability; Toxicokinetics (C_{max}, T_{max}, Plasma T_{1/2}; for parent and metabolites if available); Distribution (indicate which organs have highest levels); Rate and extent of excretion; In vitro metabolism (mention key findings, especially human:test species comparison); Toxicologically relevant compounds</p>		
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5.1 Studies on absorption, distribution, metabolism and excretion in mammals - Endpoint study record

Purpose:

Provide information on Absorption, distribution, metabolism and excretion (ADME) properties.

Currently comparative in vitro metabolism studies should be reported under "[5.8 Other toxicological studies](#)" (ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation - v.6.3 (Final) [September 2020])

Specific considerations for the reporting of metabolism studies in IUCLID:

An endpoint study record should be created for each metabolism study, filling out the standard fields of the template. In addition, metabolism studies should be entered via the DER-composer (part of the Metapath software package).

ENDPOINT_STUDY_RECORD.BasicToxicokinetics - v.8.4 (Final) [Oct. 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.DataSource

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<p>Reference</p>	<p>Indicate the bibliographic reference of the study report or publication the study summary is based on. Select item from 'Literature Reference' database or create 'New Reference'.</p> <p>If you entered in the study in the DER composer, the XML-files created with the DER-composer should be attached in the LITERATURE object, to which reference is made here. These XML-files shall contain all the data fields on material and methods and on results and discussions that were not directly reported in the present study record.</p> <p>In the field "attached documents", please use the function "select files" and attach here each XML-file associated to study referred to in this LITERATURE OBJECT.</p> <p>If you did not enter yourself the study in the DER composer because the XML-files linked to this study record are already in the list of "DER-composer XML-files" available to the Regulatory Authorities, the attachment of the XML-files is not mandatory. In such a case, please simply report the "MAP-number(s)" or the XML-file(s) in the field "other study identifier(s)" to help the Regulatory Authority identifying the corresponding XML-file(s) in the database.</p>	<p>Literature reference list</p>	<p>ENDPOINT_STUDY_RECORD.BasicToxicokinetics.DataSource.Reference</p>
<p>Materials and methods</p>	<p>Material and methods – common block</p> <p>Applicable test guideline: According to the provisions in Article 62(1) of Regulation (EC) No 1107/2009, in vivo methods can only be used where alternative methods are not suitable Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics (* Communication from the Commission in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013)</p> <p>Guideline: Guideline: Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics</p>	<p>Header 1</p>	<p>ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods</p>
<p>Objective of study</p>	<p>Indicate the purpose of the study. The field is repeatable. Select the respective toxicokinetic aspect(s) investigated.</p>	<p>Multi select open list</p>	<p>ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods</p>

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	Multiple selection is possible. If not listed, select 'other' and specify.		hods.ObjectiveOfStudyPick
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'. In the supplementary remarks field, any further explanations can be provided, e.g. for indicating that both labelled and unlabelled substances were used.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.TestMaterials.Radiolabelling
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Sex: If different sexes were used in multiple test runs recorded in the same record, select 'male/female' and differentiate in field 'Doses / concentrations'.	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Duration and frequency of treatment	Indicate duration and frequency of application, e.g. 'single application' or 'multiple application: 14 days, 2 doses per day, 5 days per week'.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DurationAndFr

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t / exposure			frequencyOfTreatmentExposure
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet, mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values / pilot study / main study.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose / concentration	Enter value or specify according to dose if different number of animals per dose / concentration, e.g. '4 in each dose / concentration group with single application; 2 f and 4 m in multiple application group'. In case of a robust study summary, include animal numbers per sex in table on animal assignment.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Positive control reference chemical	Indicate if a positive control was used and if appropriate indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.PositiveControl

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Details on study design	<p>Include further details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. Briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Details on dosing and sampling	<p>Include details on dosing and sampling. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.</p>	Text template	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DetailsOnDosingAndSampling
Statistics	<p>List parameters that were analysed by which statistical methods, computer programme used.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p>	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion
Preliminary studies	<p>Briefly describe the results of preliminary / pilot study or studies if any.</p>	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PreliminaryStudies
Main ADME results	<p>Briefly describe the most relevant results with regard to absorption, distribution, metabolism, excretion and any other aspects related to toxicokinetics. Further details can be given in the below fields 'Details on absorption', 'Details on distribution in tissues', 'Details on excretion' and/or 'Any other information on results incl. tables'.</p>		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MainAdmeResults

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	<p>If required, copy block of fields to include several parameters.</p> <p>Absorption: Include degree of absorption in %. In case of a robust study summary, include a function relating excretion of radioactivity (in urine, feces, etc.) to sampling time.</p> <p>Distribution: For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues/organs.</p> <p>Excretion: For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues and excreta including total recovery.</p> <p>Material balance: Indicate mass balance of study.</p> <p>Metabolism including clearance: describe any decrease of the test chemical concentration from the incubation vial measured to determine the clearance in vitro.</p>		
Type	Select either 'absorption', 'distribution', 'metabolism', 'excretion' or 'other:' from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MainAdmeResults.Type
Results	Briefly describe the most relevant results.	Text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MainAdmeResults.Results
Main ADME results			
Toxicokinetic / pharmacokinetic studies		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies
Details on absorption	In case of a robust study summary, describe further details on absorption. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.DetailsOnAbsorption

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	Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Details on distribution in tissues	In case of a robust study summary, describe further details on distribution including organs with highest levels. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.DetailsOnDistribution
Transfer into organs	Indicate the transfer of the radiolabelled test substance into organs. Copy this block of fields for each transfer type and/or different test runs if applicable.		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.KeyResult
Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Close list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.TestNo
Transfer type	Select type of transfer (e.g. 'blood/brain transfer') from picklist.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.TransferType
Observation	Select the qualitative description (e.g. 'distinct transfer') that characterises the observed transfer of radiolabelled test substance into the brain or spinal cord or into the placenta and on the secretion of radioactivity via the gastric mucosa, respectively. As appropriate, include quantitative data and/or any explanations in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.Observation
Transfer into organs			

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Details on excretion	In case of a robust study summary, describe further details on excretion. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.DetailsOnExcretion
Toxicokinetic parameters	Select toxicokinetic parameter from picklist and enter the corresponding value(s) with unit in the related text field. Examples: (i) Half-life 1st: 23.4 hrs (male, single administration study); (ii) C(time): 88 µg/l at 40 hrs Copy this block of fields for each parameter. If multiple test runs are recorded, enter test numbers in subfield 'Test No.'.		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters.KeyResult
Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Close d list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters.TestNo
Toxicokinetic parameters	Select parameter from drop-down list. Explanations: - AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters.ToxicokineticParameters
Toxicokinetic parameters			
Metabolite character		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion

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Metabolites identified	Indicate whether metabolites were identified.	Closed list with remarks	Endpoint.StudyRecord.BasicToxicokinetics.ResultsAndDiscussion.MetaboliteCharacterisationStudies.MetabolitesIdentified
Details on metabolites	List the metabolites identified, include percent of radioactive dose given, where they were identified, when, if applicable, how they were identified, if applicable, how much parent was present in the excreta. In case of a robust study summary, also include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). When available, include summary of metabolic pathways and attach figures in field 'Attached background material'. Mention which are major vs. minor pathways. Attach the submitter's postulated pathway as a figure. Note: Specific tables may be required.	Text area	Endpoint.StudyRecord.BasicToxicokinetics.ResultsAndDiscussion.MetaboliteCharacterisationStudies.DetailOnMetabolites
Enzymatic activity		Header 2	Endpoint.StudyRecord.BasicToxicokinetics.ResultsAndDiscussion.EnzymaticActivity
Enzymatic activity measured	Indicate the results of any enzymatic activity measured (induction, inhibition or biotransformation of test material). Identify enzyme(s) involved, rate of activity, time points measured, data from individual vials, time point for each independent run, calculated clearance and summary statistics, and method used to follow the activity. Specify whether measurements were done in vivo or in vitro, in main study or supplemental approach.	Text area	Endpoint.StudyRecord.BasicToxicokinetics.ResultsAndDiscussion.EnzymaticActivity.EnzymaticActivityMeasured
Bioaccessibility (or Bioavailability)		Header 2	Endpoint.StudyRecord.BasicToxicokinetics.ResultsAndDiscussion.Bioaccessibility
Bioaccessibility (or Bioavailability)	Indicate the results of the bio-accessibility (or bio-availability) tests, if applicable.	Text area	Endpoint.StudyRecord.BasicToxicokinetics.ResultsAndDiscussion

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Bioavailability) testing results			sion.Bioaccessibility.BioaccessibilityTestingResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ApplicantSummaryAndConclusion

Links to support material:

Test guideline: Communication from the Commission in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013

Please find specific instructions on who to structure the results of mammalian toxicology metabolism studies under the following link:

<https://www.efsa.europa.eu/en/applications/pesticides/tools>

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5.2 Acute toxicity – Endpoint summary

Purpose

Chemical (Active and Product): Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2):

- Rat LD50 oral
- Rat LD50 dermal
- Rat LC50 inhalation

Microorganism (Active and Product): Provide summary information of the most relevant study(-ies) in which the relative hazards associated with the different routes of exposure have been investigated in test mammals. The information generated through acute toxicity, pathogenicity and infectiveness testing is of particular value in assessing hazards likely to arise in accident situations and consumer risks due to exposure to possible residues.

All signs of infection and/or pathogenicity and a clearance assessment should be included.

The document should contain the information needed to be reported according to the list of end points for acute oral, dermal and inhalation toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.AcuteToxicity- v.6.2 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of toxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment
Acute toxicity: via oral route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute.LinkToRelevantStudyRecords

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	summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.		
Endpoint conclusion	Endpoint conclusion block (quality of database) Note: In case of acute studies with micro-organisms, less severe but still adverse effects are also considered during the assessment. Dose descriptor: LD50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating dose, that should be chosen.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute.EndpointConclusion
Acute toxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Note: In case of acute studies with micro-organisms, less severe but still adverse effects	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityVi

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	are also considered during the assessment. Dose descriptor: LC50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating concentration, that should be chosen.		aInhalationRoute.EndpointConclusion
Physical form	Indicate in what physical form the test material was administered.	Open list	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.EndpointConclusion.PhysicalForm
Acute toxicity: via dermal route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP)	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion block (quality of database) Note: In case of acute studies with micro-organisms, less severe but still adverse effects are also considered during the assessment.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute.EndpointConclusion

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	Dose descriptor: LD50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating dose, that should be chosen.		
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: Rat LD50 oral Rat LC50 inhalation Rat LD50 intraperitoneal/subcutaneous	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.Discussion
Justification for classification or non-classification	Not relevant for micro-organisms.	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.JustificationForClassificationOrNonClassification

5.2.1 Oral (includes acute oral toxicity to mammals) - Endpoint study record

<p>Purpose</p> <p>Chemical Active: The acute oral toxicity of the active substance shall always be reported</p> <p>Chemical Product: A test for acute oral toxicity shall be carried out, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.</p> <p>Microorganism Active: The acute oral toxicity study should permit the identification of effects following a single exposure to the microorganism, including an assessment of toxicity, pathogenicity and infectiveness, and evaluation of the clearance of the microorganism.</p> <p>Microorganism Product: An acute oral test with the plant protection product shall always be carried out only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008.</p>

ENDPOINT_STUDY_RECORD.AcuteToxicityOral - v.8.4 (Final) [September 2020]			
Name	Instructions	Type	Field Path

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Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.1 bis Acute oral toxicity - fixed dose procedure (Annex to Regulation (EC) No 440/2008). Method B.1 tris Acute oral toxicity - Acute toxic class method (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 420: Acute oral toxicity: fixed dose procedure OECD Test Guideline 423: Acute oral toxicity: acute toxic class method OECD Test Guideline 425: Acute oral toxicity: up-and-down procedure Microbial Pesticide Test Guidelines: OPPTS 885.3050 Acute Oral Toxicity/Pathogenicity Are relevant for this endpoint Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods
Test type	If possible, indicate whether the acute toxic class method, fixed dose procedure, up-and-down procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies. If neither of these test types applies, either leave field empty or use 'other': Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.LimitTest
Test material	Test material	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) Species Select name of species. If not available from picklist, select 'other' and specify.	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAnd

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	NOTE: Human data should be reported in an appropriate subsection of section 'Basic information' It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.		Methods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on oral exposure	Indicate details of oral exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnOralExposure
Doses	Include the doses including unit administered to the test animals (in CFU/ml or CFU/kg bw). As appropriate include notes in parentheses, e.g. '(male)'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

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	in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the LD50 or other.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Verification that each enumeration method is sufficiently sensitive to serve as a useful quantitative assay, for the micro-organism in tissues, organs, and body fluids	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.Preliminary
Effect levels	Provide the LD50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. Where there are significant differences in response between the sexes, include the effect levels for both. If the test was conducted according to the fixed dose procedure, include the discriminating dose, i.e. the highest out of the four fixed dose levels which can be		ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels

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	administered without causing compound-related mortality (including human kills). If no LD50 or other endpoint available from picklist is reported, but only a dose level, specify this dose using 'other' and indicate the effects observed in subfield 'Remarks on result'.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose procedure was used, select 'discriminating dose', i.e. the dose causing evident toxicity but not mortality. With the up-and-down procedure an 'approximate LD50' may be derived. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 or LD50 <10. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.BasedOn

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	Select 'not specified' if the effect concentration type is not known.		
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	In the case of a fixed dose study, summarise evidence of toxicity and mortality of any preliminary sighting study at the fixed doses administered.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings. If the fixed dose method was used, indicate if animals appeared to recover completely and state if there were no obvious substance-related signs of toxicity.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight. . Indicate if body weight loss was greater than 10%.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.BodyWeight

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Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.GrossPathology
Other findings	The following should be reported for studies with micro-organisms: - Clearance estimates (numeration of the micro-organism/toxin in the relevant tissues/organs/body fluids at different time points) - Infectivity/persistence findings (numeration and findings in affected organs/tissues, if any)	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Attached document: Detailed results in the different dose groups can be reported in Appendix F format either as an attachment and in the 'Any other information on results incl. tables'	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.OverallRemarksAttachments
Applicants summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ApplicantSummaryAndConclusion

5.2.2 Dermal – Endpoint study record

<p>Purpose</p> <p>Chemical Active: The acute dermal toxicity of the active substance shall be reported unless waiving is scientifically justified (for example where oral LD50 (2) is greater than 2 000 mg/kg). Both local and systemic effects shall be investigated.</p> <p>Chemical Product: A test for dermal toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.</p> <p>Microorganism Product: An acute percutaneous test with the plant protection product shall be conducted only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008, where applicable.</p> <p>Findings of severe skin irritation (Grade 4 erythema or oedema) in the dermal study shall be used instead of performing a specific irritation study.</p>

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ENDPOINT_STUDY_RECORD.AcuteToxicityDermal - v.8.4 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: - Method B.3 Acute toxicity (dermal) (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 402: Acute Dermal Toxicity	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods
Test type	If possible, indicate whether the fixed dose procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies. If neither of these test types applies, either leave field empty or use 'other:'. Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.LimitTest
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) Species: NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestAnimals

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	Sex: Testing in one sex (usually females) is generally considered sufficient. Provide rationale for use of males (if applicable), in field 'Details on test animals and environment conditions'.		
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure
Type of coverage	Select type of coverage used. For robust study summaries specify the area of application in field 'Details on dermal exposure'.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.TypeOfCoverage
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on dermal exposure	Indicate details of exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnDermalExposure
Duration of exposure	Indicate total duration of exposure in hours, e.g. '4 hrs'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DurationOfExposure
Doses	Include the doses including unit administered to the test animals, e.g. 50, 200, 1000 and 2000 mg/kg bw', or mention the doses after '- other:'. As appropriate include notes in parentheses, e.g. '(male)'. For a robust study summary also indicate the analytical concentrations of the test substance in the vehicle in the results table (see field 'Mortality').	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.Administr

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	regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		ationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate. If TG 402 (9 October 2017) was used, see flowchart for the testing procedure in its Annex 2.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsofStudyDesign
Statistics	Indicate the method of calculating the LD50 or other, if applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.Preliminary
Effect levels			ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAnd

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			Discussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose procedure was used, select 'discriminating dose', i.e. the dose causing evident toxicity but not mortality. With the up-and-down procedure an 'approximate LD50' may be derived. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 mg/kg bw or LD50 <10 mg/kg bw. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. For GHS classification, see 'Interpretation of results' under section 'Applicant's summary conclusion' below.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAnd

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	Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		Discussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results where required and in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If the fixed dose method was used, tabulate the evidence of toxicity and mortality (number of animals) for each sex and dose group. 'Evidence of toxicity' describes clear signs of toxicity following administration of test substance, which should be such that an increase in the exposure concentration can be expected to result in the development of severe toxic signs and probable mortality. Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Distinguish between effects at the site of application (local) and systemic effects. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAnd

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			Discussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ApplicantSummaryAndConclusion

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5.2.3 Inhalation - Endpoint study record

Purpose:

Chemical: The acute inhalation toxicity of the active substance shall be reported where any of the following apply:

- the active substance has a vapour pressure $> 1 \times 10^{-2}$ Pa at 20 °C;
- the active substance is a powder containing a significant proportion of particles of a diameter $< 50 \mu\text{m}$ ($> 1\%$ on weight basis);
- the active substance is included in products that are powders or are applied by spraying.

The head/nose only exposure shall be used, unless whole body exposure can be justified.

Microorganism Active: The acute toxicity study by inhalation should permit the identification of effects following a single exposure to the microorganism, including an assessment of toxicity, pathogenicity and infectiveness, and evaluation of the clearance of the microorganism.

Microorganism Product: The acute inhalation toxicity study must be carried out where the plant protection product:

- is used with fogging equipment,
- is an aerosol,
- is a powder containing a significant proportion of particles of diameter < 50 micrometre ($> 1\%$ on a weight basis),
- is to be applied from aircraft in cases where inhalation exposure is relevant,
- is to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 micrometre ($> 1\%$ on a weight basis),
- contains a volatile component at greater than 10%.

ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation - v.9.4 (Final) [September 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Microbial Pesticide Test Guidelines: OPPTS 885.3150 Acute Pulmonary Toxicity/Pathogenicity Are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods
Test type	If possible, indicate which method was used in the study. If neither of these test types applies, either leave field empty or use 'other:'. Note: This field may be redundant with the information	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.TestType

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	given in field 'Guideline', but is considered useful for searching reasons.		
Limit test	Indicate if the experiment was a limit test.	Close d list	ENDPOINT_STUDY_RE CORD.AcuteToxicityInh alation.MaterialsAndMet hods.LimitTest
Test material	Test material – common block	Head er 2	ENDPOINT_STUDY_RE CORD.AcuteToxicityInh alation.MaterialsAndMet hods.TestMaterials
Test animals	Select name of species. If not available from picklist, select 'other' and specify. NOTE: Human data should be reported in an appropriate subsection of section 'Basic information'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure. Sex: Provide rationale for use of females (if applicable), in field 'Details on test animals and environment conditions'.	Head er 2	ENDPOINT_STUDY_RE CORD.AcuteToxicityInh alation.MaterialsAndMet hods.TestAnimals
Administ ration / exposure		Head er 2	ENDPOINT_STUDY_RE CORD.AcuteToxicityInh alation.MaterialsAndMet hods.AdministrationExp osure
Route of administ ration	Specify the route of administration by indicating in what physical form the test material was administered. In case of intratracheal administration, specify it under 'Type of inhalation'.	Open list	ENDPOINT_STUDY_RE CORD.AcuteToxicityInh alation.MaterialsAndMet hods.AdministrationExp osure.RouteOfAdminist ration
Type of inhalatio n exposure	Indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield. In case of intratracheal administration, select other and report this in the 'remarks' field.	Open list with remar ks	ENDPOINT_STUDY_RE CORD.AcuteToxicityInh alation.MaterialsAndMet hods.AdministrationExp osure.TypeOfInhalation Exposure
Vehicle	Select the vehicle used. If not available from picklist, select 'other'.	Open list with remar ks	ENDPOINT_STUDY_RE CORD.AcuteToxicityInh alation.MaterialsAndMet hods.AdministrationExp osure.Vehicle

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Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. This field can be used for giving an additional information by selecting 'other:' or selecting a pre-defined reason why no numeric value is provided, e.g. 'not measured/tested' or 'not determinable' and entering free text explanation in the supplementary remarks field.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remark on MMAD/GSD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on inhalation exposure	Indicate details of inhalation exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt (i.e. diagram as pdf/jpeg etc.) from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnInhalationExposure
Analytical verification of test atmosphere concentrations	Indicate whether the test atmosphere concentrations and the particle size were analytically verified. For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. If any problems occurred, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.	Close list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfTestAtmosphereConcentrations
Duration of exposure	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a	Range with closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExp

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	range use both numeric fields together with the appropriate qualifier(s) if applicable.	(Decimal)	osure.DurationOfExposure
Remarks on duration	Enter any remarks related to the recorded value as appropriate.	Text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnDuration
Concentrations	Provide rationale for the selection of the starting concentration. Include the nominal concentrations the test animals were exposed to, e.g. '100, 500, 2500 and 20000 ppmV(gas)' or '0.5, 2.0, 10, 20 mg/L air (dust/mist)'. For micro-organisms (CFU/L air or some other units should be used) As appropriate include notes in parentheses, e.g. '(male)'. For robust study summaries, also provide the analytical concentrations in the results table (see field 'Mortality').	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Concentrations
No. of animals per sex per dose	Enter number or state numbers for different groups if varying, e.g. '10 (controls), 5 (in test groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the category. LC50 or other, if applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMet

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			hods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>Information on the test atmosphere characteristics can be provided e.g. Nominal concentration and Temperature</p> <p>For microorganisms: Verification that each enumeration method is sufficiently sensitive to serve as a useful quantitative assay for the MPCA tissues, organs, and body fluids should be reported</p>	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study (if performed).	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.Preliminary
Effect levels	<p>Provide the LC50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level.</p> <p>If both sexes were tested at each dose level, then the combined effect level should be stated. Where there are significant differences in response between the sexes, include the effect levels for both.</p> <p>If no LC50 or other endpoint available from picklist is reported, but only a concentration level, specify this concentration using 'other' and indicate the effects observed in subfield 'Remarks on result'.</p>		ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment.	Checkbox	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Close d list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	<p>Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose concentration was used, select 'discriminating conc.', i.e the dose causing evident toxicity but not mortality.</p> <p>Where no value could be achieved based on the</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.Endpoint

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	<p>method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LC50 >10 mg/m³ air or LC50 <10 mg/m³ air.</p> <p>For micro-organisms (CFU/L air or some other units should be used)</p> <p>An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>		
Effect level	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	<p>Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification.</p> <p>Select 'not specified' if the effect concentration type is not known.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.BaseOn
95% CL	<p>For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if relevant available.</p> <p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.cl
Exp. duration	<p>Enter numeric value. If exposure cannot be described by a single (integer) number, calculate hours and minutes reported to a decimal number, preferably based on the unit 'h (hour)', e.g. 4.15 h for 4 h, 9 min.</p>	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.ExposureDuration

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Remarks on result	This field can be used for: - giving a qualitative description of results where required and in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.Mortality
Clinical signs	Choose the corresponding clinical sign and briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. (For non TG 433 inhalation studies, do not dwell on effects that are most likely due to agonal death.) Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. If another clinical sign should be reported, choose option – other: and mention the sign as contained in the comprehensive Clinical sign lexicon provided as Table 2 in the publication by Sewell F. et al. (2015), "A global initiative to refine acute inhalation studies through the use of 'evident toxicity' as and endpoint: Towards adoption of the Fixed Concentration Procedure", Regul Toxicol Pharmacol, Vol. 73, pp. 770-779. Note if there was a reference point (e.g. NOAELs) for clinical findings.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight. Indicate if body weight loss was greater than 10%.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.GrossPathology

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Other findings	For microorganism studies report results related to: - Clearance estimates, notably in the lungs (numeration of the micro-organism/toxin in the relevant tissues/organs/body fluids at different time points) - Infectivity/persistence findings (numeration of micro-organism and findings in affected organs/tissues, if any)	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummaryAndConclusion
Executive summary		Rich text area	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummaryAndConclusion.ExecutiveSummary

5.2.4 Irritation – Endpoint summary

<p>Purpose Chemical and Microorganism: Indicate whether Skin irritation, Eye irritation is observed.</p> <p>The document should contain the information needed to be reported according to the list of end points for skin and eye irritation (SANCO/12592/2012-rev. 2, 22 March 2019).</p>
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ENDPOINT_SUMMARY.IrritationCorrosion - v.5.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.AdministrativeDataSummary

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	Description of key information: Provide a brief description of irritation studies and effects		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment
Skin irritation / corrosion		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP).</p>	Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.EndpointConclusion
Endpoint conclusion	<p>“Adverse effect observed (irritating)” should be chosen if the substance meets the classification criteria for skin irritation (Category 2).</p> <p>“Adverse effect observed (corrosive)” should be chosen if the substance meets the classification criteria for skin corrosion</p>	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.EndpointConclusion.EndpointConclusion

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	(Categories 1A, 1B or 1C). "No adverse effect observed (not irritating)" should be chosen if the substance does not meet the criteria for classification. If "No study available" is chosen, a justification needs to be provided.		
Eye irritation		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP).	Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (irritating)" should be chosen if the substance meets the classification criteria for eye irritation (Category 2). "Adverse effect observed (irreversible damage)" should be	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.EndpointConclusion.EndpointConclusion

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	<p>chosen if the substance meets the classification criteria for irreversible effects on the eye (Category 1). "No adverse effect observed (not irritating)" should be chosen if the substance does not meet the criteria for classification. If "No study available" is chosen, a justification needs to be provided.</p>		
Respiratory irritation		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion
Endpoint conclusion	<p>"Adverse effect observed (irritating)" should be chosen if the substance is found to cause respiratory irritation. "Adverse effect observed (irreversible damage)" should be chosen if the substance does not cause respiratory irritation. "No study available" should be chosen if there is no data to conclude on respiratory irritation.</p>	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion.EndpointConclusion
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.Discussion

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	Provide additional information related to the endpoint, for example: skin/eye irritant or non-irritant		
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.IrritationCorrosion.JustificationForClassificationOrNonClassification.Remarks

5.2.4.1 Skin irritation – Endpoint study record

Purpose

Chemical (Active): Provide information on the potential for skin irritancy of the active substance including, where relevant, the potential reversibility of the effects observed.

Before undertaking in vivo studies for corrosion/irritation of the active substance, a weight-of-evidence analysis shall be performed on the existing relevant data. Where insufficient data are available, they can be developed through application of sequential testing.

The testing strategy shall follow a tiered approach: (1) the assessment of dermal corrosivity using a validated in vitro test method; (2) the assessment of dermal irritation using a validated in vitro test method (such as human reconstituted skin models); (3) an initial in vivo dermal irritation study using one animal, and where no adverse effects are noted; (4) confirmatory testing using one or two additional animals.

Chemical (Product): The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008, for which skin irritation properties of all components shall be provided or reliably predicted with a validated method.

Microorganism (Product): The skin irritancy of the plant protection product, including the potential reversibility of the effects observed, must always be determined where the co-formulants are not expected to be skin irritant or the microorganism is shown not to be skin irritant or where it is likely, as indicated in the test guideline, that severe skin effects can be excluded.

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ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion - v.8.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.DataSource
Materials and methods	<p>Material and methods – common block</p> <p>Applicable test guideline: Method B.4 Acute toxicity: dermal irritation/corrosion (Annex to Regulation (EC) No 440/2008).</p> <p>OECD TG 430 / Method B.40 In vitro skin corrosion: transcutaneous electrical resistance test (TER) (Annex to Regulation (EC) No 440/2008).</p> <p>OECD TG 431 / Method B.40 bis In vitro skin corrosion: human skin model test (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 404: Acute Dermal Irritation/Corrosion</p> <p>OECD Test Guideline 431: In vitro Skin Corrosion: Human Skin Model Test</p> <p>OECD Test Guideline 430: In vitro Skin Corrosion: Transcutaneous Electrical Resistance Test</p> <p>OECD Test Guideline 435: In vitro Membrane Barrier Test Method for Skin Corrosion</p> <p>OECD Test Guideline 439: In vitro Skin Irritation: Reconstructed Human Epidermis Test Method</p> <p>OECD TG 439 / Method B.46 In vitro skin irritation: reconstructed human epidermis model test (Annex III of Regulation (EC) No 761/2009 (7).</p>	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestMaterials

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In vitro test system		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem
Test system	Select as appropriate. If not available from picklist, select 'other:' and specify. Further information can be given in the supplementary remarks field. Use of other than the test systems recommended by the test guidelines is to be considered as deviation from guideline and should be noted and justified in the field "Test guideline - Deviations".	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.TestSystem
Source species	Select as appropriate. Indicate the species used as source of the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.SourceSpecies
Cell type	For in vitro tests, e.g. according to OECD Guidelines 431 and 439, indicate the cell type used to construct the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.CellType
Cell source	For in vitro tests, e.g. according to OECD Guidelines 431 and 439, indicate the source of the cells used to construct the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.CellSource
Source strain	For in vitro tests, e.g. according to OECD Guideline 430, indicate the strain used as source of the test system. If not available from picklist, select 'other:' and specify. Use of other than the strain recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.SourceStrain
Details on animal used as source of test system	For in vitro tests, e.g. according to OECD Guideline 430, give details on the animal used as source of the skin discs. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DetailsOnAnimalUsedAsSourceOfTestSystem

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	- Water: Describe type (e.g. drinking water) and whether it was provided ad libitum.		
Justification for test system used	Provide a justification for the test system used	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.JustificationForTestSystemUsed
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.Vehicle
Details on test system	<p>For in vitro tests, e.g. according to OECD Guidelines 430, 431, 435 or 439, indicate details on the test system used including test conditions. Select freetext template for the respective type of study (i.e. Transcutaneous electrical resistance test (TER) (e.g OECD TG 430) or Artificial membrane barrier test method (e.g OECD TG 435) or Human skin model test (e.g OECD TG 431) or Reconstructed human epidermis test method) (e.g OECD TG 439)) and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Explanations:</p> <ul style="list-style-type: none"> - SKIN DISC PREPARATION (if Transcutaneous electrical resistance test): Summarise the procedure used to prepare the skin discs and, for each animal skin used as source for skin discs, indicate the electrical resistances obtained with two of the isolated skin discs before testing (should be $\geq 10 \text{ k}\Omega$) - RECONSTRUCTED HUMAN EPIDERMIS (RHE) TISSUE: For human skin model tests, e.g. according to OECD Guidelines 431 and 439, indicate the Reconstructed human Epidermis (RhE) tissue model used, batch number(s) used, the production date, the shipping date, the delivery date, and the date of initiation of testing. - TEMPERATURE USED FOR TEST SYSTEM: Indicate the temperature used during treatment / exposure (e.g. room temperature, 25°C, 37°C, etc). If more than one temperature was used, indicate the different sequential temperatures used and the exact exposure time at each temperature. - REMOVAL OF TEST MATERIAL AND CONTROLS: Indicate the volume (if applicable) and number of 	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DetailsOnTestSystem

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	<p>washing steps used to remove the test item from the test system after treatment / exposure. Indicate if any observable damage was induced by the washing procedure. Indicate any modification to the validated SOP introduced in the washing procedure.</p> <p>- FUNCTIONAL MODEL CONDITIONS WITH REFERENCE TO HISTORICAL DATA (if human skin model test): Provide details on viability (negative control OD values of each tissue batch in comparison to historical acceptability ranges); barrier function (for each tissue batch, indicate the IC50 obtained with 18 h treatment with SDS or the ET50 obtained with treatment with 1% Triton X-100 in comparison to historical acceptability ranges); morphology (number and type of viable epithelial cell layers (basal layer, stratum spinosum, stratum granulosum) and the approximate number of layers of the stratum corneum, as assessed by histological examination); contamination (indicate if the tissue batches used were free of contamination by bacteria, viruses, mycoplasma or fungi, reproducibility (indicate the reproducibility of the negative and positive controls over time)</p> <p>- PREDICTION MODEL / DECISION CRITERIA: Describe and justify the prediction model / decision criteria used to derive the corrosion/irritation classification</p>		
Control samples	<p>Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information.</p> <p>Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control, a concurrent negative control, non-specific colour controls and non-specific MTT reduction controls.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.ControlSamples
Amount/ concentration applied	<p>Give the amount(s) of substance / controls applied (volume or weight with unit) and the concentration of the substance, controls and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.AmountConcentrationApplied
Duration of treatment	<p>Indicate length of time test material was in contact with test system, e.g. '3 min. ' or '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem

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t / exposure			stem.DurationOfTreatmentExposure
Duration of post-treatment incubation (if applicable)	Indicate length of post-treatment incubation period as applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DurationOfPostTreatmentIncubationIfApplicable
Number of replicates	Indicate the number of replicate tissues/skin discs used in each treatment / exposure and control groups.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.NumberOfReplicates
Test animals	<p>Test animals (OHT: Repeated dose toxicity)</p> <p>Species: For in vitro tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify.</p> <p>Use of other than the species recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields</p> <p>NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'.</p> <p>It can be useful to document, in section 'Skin irritation / corrosion', that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.</p>	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestAnimals
Test system		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem
Type of coverage	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.TypeOfCoverage
Preparation of test site	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAnd

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		remarks	Methods.TestSystem.P reparationOfTestSite
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_R ECORD.SkinIrritationC orrosion.MaterialsAnd Methods.TestSystem. Vehicle
Controls	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information). Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control and a concurrent negative control.	Multi select open list with remarks	ENDPOINT_STUDY_R ECORD.SkinIrritationC orrosion.MaterialsAnd Methods.TestSystem. Controls
Amount / concentration applied	Give the amount(s) of substance applied (volume or weight with unit) and the concentration of the substance and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_R ECORD.SkinIrritationC orrosion.MaterialsAnd Methods.TestSystem. AmountConcentration Applied
Duration of treatment / exposure	Indicate length of time test material was in contact with test animal, including unit, e.g. '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_R ECORD.SkinIrritationC orrosion.MaterialsAnd Methods.TestSystem. DurationOfTreatmentE xposure
Observation period	Indicate length of observation period.	Multi-line text	ENDPOINT_STUDY_R ECORD.SkinIrritationC orrosion.MaterialsAnd Methods.TestSystem. ObservationPeriod
Number of animals	Indicate number of animals used.	Multi-line text	ENDPOINT_STUDY_R ECORD.SkinIrritationC orrosion.MaterialsAnd Methods.TestSystem. NumberOfAnimals
Details on study design	For in vivo tests, e.g. according to OECD Guideline 404, give details on study design. Describe the method of calculation of maximum average score given in the results table used (if applicable). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for	Text template	ENDPOINT_STUDY_R ECORD.SkinIrritationC orrosion.MaterialsAnd Methods.TestSystem. DetailsOnStudyDesign

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	evaluating this study summary or that are requested by the respective regulatory programme.		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion
In vitro		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro
Results	<p>Indicate the overall irritation / corrosion results for the test substance in terms of tissue viability, transcutaneous electrical resistance, penetration time or other. Copy this block of fields as appropriate.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables".</p> <p>(Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'In vivo, depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.</p> <p>Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results
Irritation / corrosion parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field, e.g. "based on optical density measurement".	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results

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			ts.IrritationCorrosionParameter
Run / experiment	Indicate the run / experiment the measurement relates to, if more than one run / experiment was performed and the length of time the test material was in contact with the test system, if different exposure time periods were applied in different test runs of this study. Examples: Run 1 (duration of exposure: 2 hours); Run 1, replicate 1 (duration of exposure: 2 hours), Mean of three runs with two replicates each.	Text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.RunExperiment
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.Value
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. without test substance, with/without solvent) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) is valid, i.e. substance(s) with known lack of irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) is valid, i.e. substance(s) with known irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.RemarksOnResults
Results			
Other effects / acceptan	Use freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Other

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<p>ce of results</p>	<p>(e.g. visible damage on test system, no visible damage on test system, direct-MTT reduction, colour interference with MTT, etc). Discuss the applicability of the test method to test colorants and/or direct MTT-reducers in reference to the %NSC and/or %NSMTT values reported in the block of fields above.</p> <p>- DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'.</p> <p>- ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative control, positive control, and variability between replicate measurements) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		<p>EffectsAcceptanceOfResults</p>
<p>In vivo</p>		<p>Header 2</p>	<p>ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo</p>
<p>Results</p>	<p>For in vivo test results, provide individual time point scores per animal and mean scores. If reported or required by the relevant legislation, indicate overall irritation / corrosion results in terms of an Overall irritation score, Primary dermal irritation index or other (specify). Copy this block of fields as appropriate. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'In vivo, depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl.</p>		<p>ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results</p>

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	tables". Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		
Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Parameter
Basis	Indicate if the score is the mean of all scoring results for the parameter selected on the preceding subfield or based on individual animals, e.g. animal #1. Option 'animal:' allows to enter text/numbers in the related supplementary remarks field, e.g. 'animal: #1, 2 and 3').	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Basis
Time point	Indicate the time point(s) the score relates to by selecting the appropriate value from the picklist, e.g. '24' or '24/48/72 h' (if the same score applies), and in the following field, the unit.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.TimePoint
Score	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Score
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Scale
Reversibility	Indicate whether the irritation was reversible or not. As appropriate use supplementary remarks field linked to the picklist item selected for indicating average time for (non-)reversibility.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Reversibility
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' An explanation should be provided when there was a	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.RemarksOnResults

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	need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.		
Results			
Irritant / corrosive response data	For robust study summaries or as requested by the regulatory programme, tabulate the raw data for each individual animal at each observation time up to removal of each animal from the test (unless these data are given in above block of fields 'Irritation / corrosion results'). Upload predefined table(s) if any in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). In field "Details on study design (in vivo)", describe the method of calculation used. Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.IrritationCorrosionResponseData
Other effects	Use freetext template and delete/add elements as appropriate. For in vivo tests, e.g. according to OECD Guideline 404, describe any other adverse local (e.g. defatting of skin) and systemic effects in addition to dermal irritation or corrosion.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.OtherEffects
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ApplicantSummaryAndConclusion

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5.2.4.2 Eye irritation – Endpoint study record

Purpose

Chemical: The eye irritancy of the active substance shall always be tested, except where it is likely that severe effects on the eyes may be produced based on criteria listed in the test methods. The results of the study shall provide the potential of eye irritancy of the active substance including, where relevant, the potential reversibility of the effects observed. Before undertaking in vivo studies for eye corrosion/irritation of the active substance, a weight-of-evidence analysis shall be performed on the existing relevant data.

Where available data are considered insufficient, further data may be developed through application of sequential testing. The testing strategy shall follow a tiered approach:

- (1) the use of an in vitro dermal irritation/corrosion test to predict eye irritation/corrosion;
- (2) the performance of a validated or accepted in vitro eye irritation study to identify severe eye irritants/corrosives (such as Bovine Corneal Opacity and Permeability (BCOP) assay, Isolated Chicken Eye (ICE) assay, Isolated Rabbit Eye (IRE) assay, Hen's Egg Test - Chorio-Allantoic Membrane assay (HET-CAM)), and where negative results are obtained, the assessment of eye irritation using an in vitro test method for identification of non irritants or irritants, and where not available;
- (3) an initial in vivo eye irritation study using one animal, and where no adverse effects are noted;
- (4) confirmatory testing using one or two additional animals.

Microorganism (product): The test will provide the potential for eye irritation of the plant protection product, including the potential reversibility of the effects observed. The eye irritancy of the plant protection product must be determined, where the co-formulants are suspected to be eye irritant, except where the microorganism is eye irritant or where it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.

ENDPOINT_STUDY_RECORD.EyeIrritation - v.8.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.5 Acute toxicity: eye irritation/corrosion OECD 405 OECD 437 OECD 438	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods

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	<p>Method B.47 Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants (</p> <p>Method B.48 Isolated chicken eye test method for identifying ocular corrosives and severe irritants</p>		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestMaterials
Test animals / tissue source		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals
Species	<p>Select as appropriate. For in vitro / ex vivo tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify. Use of other than the species recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in section 'Irritation / corrosion', that human data are provided by creating a record and referring to the human data in block 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.</p>	Open list	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.Strain
Details on test animals or tissues and environmental conditions	<p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations:</p> <ul style="list-style-type: none"> - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - Food quality and water quality: provide analytical information on the nutrient and dietary contaminant 	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.OrganismDetails

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	<p>levels. Similarly provide analytical information on the drinking water used in the study.</p> <p>- IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing).</p>		
Test system		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.Vehicle
Controls	<p>Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expirations date, purity and any other relevant information.</p> <p>Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control and a concurrent negative control.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.Controls
Amount / concentration applied	Give the amount(s) of substance / controls applied (volume or weight with unit) and the concentration of the substance, controls and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.AmountConcentrationApplied
Duration of treatment / exposure	Indicate length of time test material was in contact with animal/cell/tissue including unit, e.g. '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DurationOfTreatmentExposure
Observation period (in vivo)	Indicate length of observation period.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.ObservationPeriod
Duration of post-treatment incubation	Indicate length of post-treatment incubation period as appropriate.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DurationOfPostTreat

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n (in vitro)			mentIncubationInVitro
Number of animals or in vitro replicates	Indicate number of animals used (if in vivo) or, in the case of in vitro tests, the number of replicate tissues used in each treatment / exposure and control group.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.NumberOfAnimals
Details on study design	Select freetext template for the respective type of study (i.e. In vivo test method, In vitro test method (BCOP) or In vitro test method (ICE) and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DetailsOnStudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion
In vitro		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro
Results	Indicate the overall irritation / corrosion results for the test substance in terms of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). Copy this block of fields for reporting several scores, e.g. means of individual replicates. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'in vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy

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	entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		
Irritation parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. For instance, in the case of morphological effects, specify if and to what severity pitting of corneal epithelial cells, loosening of epithelium, roughening of the corneal surface and sticking of the test substance to the cornea occurred.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.IrritationParameter
Run / experiment	Indicate the run / experiment the measurement relates to, if more than one run / experiment was performed and the length of time the test material was in contact with the test system, if different exposure time periods were applied in different test runs of this study. Examples: Run 1 (duration of exposure: 10 min.); Run 1, replicate 1 (duration of exposure: 10 min.), Mean of three runs with two replicates each.	Text	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.RunExperiment
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.Value
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. vehicle only without test substance) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) demonstrated lack of irritation/corrosion of the known non-irritant/non-corrosive substance, and/or that the negative control falls within the acceptance criteria range as described in the TG. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) demonstrated irritation/corrosive effects of the known irritant/corrosive substance and/or that positive control results fall within the acceptance criteria as described in	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStu

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	the TG. Relevant remarks can be given in the supplementary remarks field.		dy.PositiveControls Valid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsofExVivoInVitroStudy.RemarksOnResult
Results			
Other effects / acceptance of results	Select freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system) - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative and positive control) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.OtherEffectsAcceptanceOfResults
In vivo		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo
Results	Indicate the scores of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). In subfield "Basis of irritation parameter" indicate if the score is an average value (i.e. mean), or for a give animal, or other. Copy this block of fields for reporting several scores, e.g. means or for individual animals. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults

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	<p>test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'in vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.</p> <p>Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		
Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Parameter
Basis	Indicate if the score is the mean of all scoring results for the parameter selected on the preceding subfield or based on individual animals, e.g. animal #1. Option 'animal:' allows to enter text/numbers in the related supplementary remarks field, e.g. 'animal: #1, 2 and 3').	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Basis
Time point	Indicate the time point(s) the score relates to by selecting the appropriate value from the picklist, e.g. '24' or '24/48/72 h' (if the same score applies), and in the following field, the unit.	Open list	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.TimePoint
Score	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Score
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Scale
Reversibility	Indicate whether the irritation was reversible or not. As appropriate use supplementary remarks field linked to the	Open list	ENDPOINT_STUDY_RECORD.EyeIrrit

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	picklist item selected for indicating average time for (non-)reversibility.	with remarks	ion.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Reversibility
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.RemarksOnResults
Results			
Irritant / corrosive response data	For robust study summaries or as requested by the regulatory programme, tabulate the raw data for each individual animal at each observation time (unless these data are given in above block of fields 'Irritation / corrosion results'). Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Describe the method of calculation of maximum average score given in the results table. Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResponseData
Other effects	Select freetext template and delete/add elements as appropriate. Describe any other relevant results including lesions and clinical observations, ophthalmoscopic and histopathological findings, effects of rinsing or washing if applicable.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.OtherEffects
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.ApplicantSummaryAndConclusion

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5.2.5 Skin sensitization - Endpoint summary

Purpose:

Chemical (Active) - Microorganism (Product): Provide summary information of the most relevant study(ies) from which the key value for active substance assessment is extrapolated. Provide only the most relevant details e.g. Sensitising (state method, e.g. LLNA) related to the potential of the chemical active or microorganism product to provoke sensitisation.

Microorganism (Active): The available methods for testing dermal sensitisation are not suitable for testing microorganisms, and there are no validated test methods for sensitisation by inhalation. As a consequence, all microorganisms will be labelled as potential sensitisers, unless the applicant wants to demonstrate the non-sensitising potential by submitting data. Therefore, this data requirement should be regarded as optional, on a provisional basis.

The document should contain the information needed to be reported according to the list of end points for skin sensitisation (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.Sensitisation - v.4.0 (Final) [April 2019]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of the study and the potential of the micro-organism to provoke sensitisation reactions.	Header 1	ENDPOINT_SUMMARY.Sensitisation.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment
Skin sensitisation		Header 2	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected:	Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.LinkToRelevantStudyRecords

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	quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.		
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion
Endpoint conclusion	<p>"Adverse effect observed (sensitising)" should be chosen if the micro-organism shows effects of skin sensitisation .</p> <p>"No adverse effect observed (not sensitising)" should be chosen if the substance does not show effects of skin sensitisation.</p> <p>If "No study available" is chosen, a justification needs to be provided.</p>	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.EndpointConclusion
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified 	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.AdditionalInformation

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	to be relevant for the assessment. If there is no additional information to be reported this field may be left empty.		
Respiratory sensitisation		Header 2	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP).	Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (sensitising)" should be chosen if the micro-organism shows effects of respiratory sensitisation. "No adverse effect observed (not sensitising)" should be chosen if the substance does not show effects of respiratory sensitisation. If "No study available" is chosen, a justification needs to be provided.	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion.EndpointConclusion

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Additional information	Provide additional information related to the endpoint, for example: sensitising (state source of evidence, e.g. type of study, clinical data, etc)	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion.AdditionalInformation
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Sensitisation.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Sensitisation.JustificationForClassificationOrNonClassification.Remarks

5.2.5 Skin sensitization - Endpoint study record

Purpose:

Chemical (Active): Provide sufficient information to assess the potential of the active substance to provoke skin sensitisation reactions. The study shall always be carried out, except where the active substance is a known sensitiser. The local lymph node assay (LLNA) shall be used, including where appropriate the reduced variant of the assay. In case the LLNA cannot be conducted, a justification shall be provided and the Guinea Pig Maximisation Test shall be performed. Where a guinea pig assay (Maximisation or Buehler), meeting OECD guidelines and providing a clear result, is available, further testing shall not be carried out for animal welfare reasons. Since an active substance identified as a skin sensitiser can potentially induce hypersensitivity reaction, potential respiratory sensitisation should be taken into account when appropriate tests are available or when there are indications of respiratory sensitisation effects. Note: the sections of this document to be completed are dependent on the endpoint selected

Chemical (Product): The skin sensitisation test shall be carried out unless the active substances or co-formulants are known to have sensitising properties or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin sensitisation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the sensitising potential of the total mixture.

Microorganisms (Active): Provide sufficient information to assess the potential of the microorganism to provoke sensitisation reactions by inhalation as well as with dermal exposure. A maximised test has to be performed.

Microorganism (Product): The test will provide sufficient information to assess the potential of the plant protection product to provoke skin sensitisation reactions. The test must be carried out where the co-formulants are suspected to have skin sensitising properties, except where the microorganism(s) or the co-formulants are known to have skin sensitising properties.

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ENDPOINT_STUDY_RECORD.SkinSensitisation - v.10.5 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.DataSource
Materials and methods	<p>Material and methods – common block</p> <p>Applicable test guideline: OECD 406</p> <p>Method B.42 Skin sensitisation: Local lymph node assay (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.6 Skin sensitisation (Annex to Regulation (EC) No 440/2008).</p> <p>OECD 429</p> <p>OECD 442A + 442B.</p>	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods
Type of study	Select type of study as appropriate. If another than the LLNA test system was used, a justification may be required in the following field.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.TypeOfStudy
Justification for non-LLNA method	Provide a justification for the use of another than the LLNA test system (if in vivo), if the relevant legislation so requires. For instance it could be argued that the LLNA method was not available yet by the time the study was conducted or that the LLNA test is not suitable for that substance or that an appropriate guinea pig maximisation test is available which would not justify conducting an additional LLNA due to animal welfare. Refer to the relevant legislation-specific guidance document.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.JustificationForNonLLNAMethod
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.TestMaterials
In vitro test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem
Details of test system	If standard cell lines not used, please select 'other:' and specify in the freetext field exact details of the cell line used.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I

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			nVITROTestSystem.DetailsTestSystem
Details on the study design	<p>PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used (EC/CAS, purity, treatment of the material) etc. If stable dispersion is not obtained and the test solution is still used, add an explanation why this is not considered to affect the validity of the study.</p> <p>DOSE RANGE FINDING ASSAY: describe the highest concentration used for the dose range finding assay and how appropriate doses were selected taking solubility and cytotoxicity into account. Specify which solvents were used and finally selected and how cytotoxicity assessment was performed.</p> <p>APPLICATION OF THE TEST CHEMICAL AND CONTROL SUBSTANCES: describe the application of test chemical and control substance exposure conditions in detail.</p> <p>SEEDING AND INCUBATION: describe the seeding and incubation conditions and whether precipitation was noted.</p> <p>MEASUREMENT OF CELL SURFACE EXPRESSION/LUCIFERASE ACTIVITY: describe the steps taken to ensure the suitability of the cell surface marker expression/luciferase activity measurements for the test chemical, including solvents used</p> <p>LUCIFERASE ACTIVITY MEASUREMENTS: describe the steps taken to ensure the suitability of the luciferase activity measurements for the test chemical, including solvents used</p> <p>DATA EVALUATION: report the cytotoxicity measurements taken and the prediction model to be used.</p>	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I nVITROTestSystem.DetailsOnStudyDesign
Vehicle / solvent control	Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I nVITROTestSystem.VehicleSolventControl
Negative control	Select the negative control as appropriate. If no negative control required (Keratinosens), select 'not applicable'. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I nVITROTestSystem.NegativeControl
Positive control	Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I

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	detailed justification for not using a standard positive control.		nVivoTestSystem.PositiveControl
In chemico test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem
Details of test system	Indicate the purity of the peptides used in the 'remarks' field. If standard peptides are not used, please select 'other:' and specify in the freetext field the exact details of the peptide used and supporting information on the scientific validity of their use.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.DetailsTestSystem
Details on the study design	PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used (EC/CAS, purity, treatment of the material) etc. INCUBATION: describe the incubation conditions and whether precipitation was noted. PREPARATION OF THE HPLC: describe the steps taken to ensure the suitability of the HPLC for the test chemical, including solvents used DATA EVALUATION: report the UV wavelength used for peptide/derivative detection.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.DetailsOnStudyDesign
Vehicle / solvent	Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.VehicleSolvent
Positive control	Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard positive control.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.PositiveControl
In vivo test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem
Test animals		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals
Species	Select as appropriate. For in vitro tests, indicate the species used as source of the test system. If not	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation

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	<p>available from picklist, select 'other' and specify. NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Sensitisation data'.</p> <p>It can be useful to document, in section 'Skin sensitisation', that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.</p>		.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify. In the supplementary remarks field, also specify the substrain if not specified by picklist item. Provide rationale for choice of strain and substrain if deviating from the ones recommended by the test guideline used.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Strain
Sex	Select as appropriate. If females were used, indicate in field "Details on test animals and environmental conditions" whether nulliparous and non-pregnant.	Closed list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Sex
Details on test animals and environmental conditions	<p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Explanations:</p> <ul style="list-style-type: none"> - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing). 	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.DetailsOnTestAnimalsAndEnvironmentalConditions
Study design: in vivo (non-LLNA)		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA
Induction	Record the vehicle, test substance concentrations used for induction exposure(s), the total amount of substance applied and the day(s) and duration of the induction. Copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Induction

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Route	Indicate the route of induction exposure.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA. Induction.Route
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided.	Open list with remarks	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA. Induction.Vehicle
Concentration / amount	Provide the test substance concentrations used for induction exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA, mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted).	Multi-line text	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA. Induction.Concentratio nAmount
Day(s)/duration	Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8).	Text	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA. Induction.DaySDuratio n
Adequacy of induction	Indicate if the test concentration used for the induction exposure was well-tolerated systemically and the highest to cause mild-to-moderate skin irritation, or if the highest technically applicable concentration used. If the substance is a non-irritant, indicate in field 'Details on study design' the appropriate pre-treatment applied for causing local irritation.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA. Induction.AdequacyOfI nduction
Induction			
Challenge	Record the vehicle, test substance concentrations used for challenge exposure(s), the total amount of substance applied and the day(s) and duration of challenge. Copy this block of fields as appropriate. Consecutive numbers can be entered in the subfield "No." for indicating multiple challenges.		ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA. Challenge
No.	For indicating multiple challenges or rechallenge select a consecutive number from drop-down list.	Close list	ENDPOINT_STUDY_RE CORD.SkinSensitisation .MaterialsAndMethods.I nVivoTestSystem.Study

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			DesignInVivoNonLLNA.Challenge.No
Route	Indicate the route of challenge exposure.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.Route
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.Vehicle
Concentration / amount	Provide the test substance concentrations used for challenge exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA, mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted).	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.ConcentrationAmount
Day(s)/duration	Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8).	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.DaySDuration
Adequacy of challenge	Indicate if the test concentration used for the challenge exposure was the highest non-irritation dose.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.AdequacyOfChallenge
Challenge			
No. of animals per dose	Provide number of animals per dose or range if different numbers were used, e.g. '10 (controls), 10-20 (in test groups)'.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.NoOfAnimalsPerDose
Details on study design	For in vivo non-LLNA sensitisation tests, describe any range finding tests (pilot study) and for the main study the induction and challenge procedures including the	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I

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	<p>type of information given in the freetext template. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Example for Freund's Complete Adjuvant (FCA) test (partly adopted from OECD 406):</p> <ul style="list-style-type: none"> - A. INDUCTION EXPOSURE - No. of exposures: 5 - Exposure period: - - Test groups: TS in FCA - Control group: FCA only - Site: R flank - Frequency of applications: every 2nd day - Duration: 0-8 d - Concentrations: same throughout B. CHALLENGE EXPOSURE - No. of exposures: 2 - Day(s) of challenge: 22 & 35 - Exposure period: - - Test groups: TS - Control group: TS - Site: L flank - Concentrations: 4 different - Evaluation (hr after challenge): 24, 48, 72 		nVivoTestSystem.Study DesignInVivoNonLLNA.DetailsOnStudyDesign
Challenge controls	Discuss the use of a challenge (i.e. naive) control group: number and sex of animals, dose for challenge application.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA.ChallengeControls
Positive control substance(s)	Indicate if positive control substance(s) was/were used. If yes, describe the positive control(s) in supplementary field as appropriate. If no, describe any periodic or historic positive control(s).	Closed list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoNonLLNA.PositiveControlSubstances
Study design: in vivo (LLNA)		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I nVivoTestSystem.Study DesignInVivoLLNA
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle	Open list with	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.I nVivoTestSystem.Study

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	used is not from the list provided in the test guideline, a rationale must be provided.	remarks	DesignInVivoLLNA.Vehicle
Concentration	Describe dose selection, i.e. at least 3 consecutive concentrations (100%, 50%, 25% 10%, 5%, 2.5%, 1%, 0.5% etc.) of the test substance. Adequate scientific rationale should accompany the selection of the concentration series used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Concentration
No. of animals per dose	Provide number of animals per dose or range if different numbers were used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.NoOfAnimalsPerDose
Details on study design	<p>For LLNA, LLNA:DA or LLNA:BrdU-ELISA, describe details on materials and methods as indicated in the freetext template. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <ul style="list-style-type: none"> - Details on radio isotope: to be included in field 'Details on test material' - RANGE FINDING TESTS: Briefly describe compound solubility, irritation and lymph node proliferation response if significant. - PRE-SCREEN TESTS: Briefly describe compound solubility, irritation, systemic toxicity (changes in: nervous system function, behaviour, respiratory patterns, food and water consumption), ear thickness measurements, erythema scores (0-3 on any day of measurement). <p>MAIN STUDY</p> <ul style="list-style-type: none"> - ANIMAL ASSIGNMENT AND TREATMENT: Indicate name of test method used. Comment on criteria used to consider a positive response. - TREATMENT PREPARATION AND ADMINISTRATION: Describe dose preparation and administration. (e.g. for LLNA:BrdU-ELISA 25 µl of compound x was applied to the entire dorsal surface of each ear of each mouse. The application was repeated on days 2 and 3). On day 5 an injection of 0.5 ml (5mg/mouse) of BrdU (10 mg/ml) solution was made inter-peritoneally for each experimental mouse. Twenty-four hours later, the draining auricular lymph node of each ear was excised into PBS (indicate individual animal approach or pooled animal approach). A single cell suspension of lymph 	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.DetailsOnStudyDesign

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	node cells was prepared from each mouse (describe method of cell suspension).		
Positive control substance(s)	Indicate the positive control substance(s) used and give additional remarks in supplementary field as appropriate, e.g. the concentration used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.PositiveControlSubstances
Statistics	Provide the statistical procedures employed (e.g., linear regression analysis or William's test to assess dose-response trends; Dunnett's test to make pairwise comparisons).	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion
Positive control results	Discuss the positive control results and demonstrate that the laboratory has the capability to identify positive dermal sensitizers.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.PositiveControlResults
In vitro / in chemico		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico
Results	Indicate the test results. Copy this block of fields as appropriate. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results

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	domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.KeyResult
Group		Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.Group
Run / experiment	Indicate the run / experiment the measurement relates to.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.RunExperiment
Parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. Please include EC150 and EC200 values, if those can be calculated.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.Parameter
Value	Indicate also the unit of measurement e.g. μM , mM, $\mu\text{g/ml}$, mg/ml etc.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.Value
At concentration		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.AtConcentration
Cell viability		Text area	ENDPOINT_STUDY_RECORD.SkinSensitisation

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			.ResultsAndDiscussion. InVitroInChemico.Results.CellViability
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. without test substance, with/without solvent) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion. InVitroInChemico.Results.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) is valid, i.e. substance(s) with known lack of irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion. InVitroInChemico.Results.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) is valid, i.e. substance(s) with known irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion. InVitroInChemico.Results.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion. InVitroInChemico.Results.RemarksOnResults
Results			
Outcome of the prediction model	For DPRA, the mean peptide % depletion values have been specified for each reactivity group in the test guideline for each prediction model.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion. InVitroInChemico.PredictionModelOutcome
Other effects / acceptance of results	Use freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system) - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion. InVitroInChemico.OtherEffectsAcceptanceOfResults

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	<p>- ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative control, positive control, and variability between replicate measurements) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
In vivo (non-LLNA)		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest
Results	<p>Record the results of in vivo non-LLNA tests at the different readings for each test or control group used. Copy this block of fields as appropriate. Present the scores from the challenge responses in a table. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.</p>		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.KeyResult
Reading	<p>Select from drop-down list.</p>	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.Reading
Hours after challenge	<p>Enter numeric value.</p>	Decimal	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.HoursAfterChallenge

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Group	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.Group
Dose level	If more than one concentration was tested at challenge, specify the concentration(s) the reading refers to, e.g. '0.15 g of a 10% aqueous solution'. Several dose levels can be given if the results reported in this block of fields is the same for all challenge groups, e.g. '0.15 or 0.3 g of a 10% aqueous solution'.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.DoseLevel
No. with + reactions	Enter numeric value.	Integer	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.NoWithReactions
Total no. in group	Enter numeric value.	Integer	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.TotalNoInGroup
Clinical observations	Briefly describe relevant clinical observations.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.ClinicalObservations
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.RemarksOnResults
Results			
In vivo (LLNA)		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA
Results	Indicate the cell proliferation results for the test substance, i.e. either ATP (measured adenosine		ENDPOINT_STUDY_RECORD.SkinSensitisation

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	<p>triphosphate content of lymphocytes) or BrdU (measured 5-bromo-2-deoxyuridine content in DNA of lymphocytes) or DPM (incorporated radioactivity as disintegrations per minute) or other. Copy this block of fields as appropriate.</p> <p>(Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Cellular proliferation data / Observations" and/or upload a table in the field "Any other information on results incl. tables".</p> <p>Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		.ResultsAndDiscussion. InVivoLLNA.Results
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion. InVivoLLNA.Results.KeyResult
Parameter	Select type of parameter from picklist, if applicable, i.e. either SI (stimulation index) or EC3 (estimated concentration of a test substance needed to produce a stimulation index of three) or ECt (estimated concentration of a test substance needed to produce a stimulation index that is indicative of a positive response) or other (specify). Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion. InVivoLLNA.Results.Parameter
Value	Provide the numeric value or a range of values if reported so. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion. InVivoLLNA.Results.Value
Variability	Indicate the standard deviation or other appropriate measure of variability that takes into account the inter-	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation. .ResultsAndDiscussion.

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	animal variability in both the test substance and control groups when using the individual animal approach.		InVivoLLNA.Results.Variability
Test group / Remarks	Indicate the concentration of the test material, the run / experiment number the calculated value relates to and any other relevant information. Examples: Exp. 1 (0%); Exp. 1 (0.5%); Exp. 1 (1%), etc. or Mean of three runs (0%), etc.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.TestGroupRemarks
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.RemarksOnResults
Results			
Cellular proliferation data / Observations	For robust study summaries or as requested by the regulatory programme, tabulate the raw data (unless these data are given in above block of fields 'Stimulation index / EC value') and indicate any relevant observations. Use freetext template and delete/add elements as appropriate. Alternatively or in addition refer to appropriate table(s), which were uploaded in the rich text field 'Any other information on results incl. tables'. Use predefined table if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them (e.g. '... see Table 1'). Provide the results of cellular proliferation measurements (DPM values for conventional LLNA or ATP content values for LLNA: DA or BrdU content values for LLNA: BrdU-ELISA). Comment on dose-response trends and comparisons with the vehicle control group. Give statistical comparisons of group mean measurements compared to control. Indicate whether results are from the individual animals or pooled. Indicate whether the overall result is positive or negative. Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.CellularProliferationDataObservations
Any other information on results	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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incl. tables			
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.ApplicantSummaryAndConclusion

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5.2.6 Phototoxicity – Endpoint Summary

Purpose:

State if 'not required' or 'not phototoxic/probably phototoxic/phototoxic'

The document should contain the information needed to be reported according to the list of end points for phototoxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

ENDPOINT_SUMMARY.Phototoxicity - v.1.2 (Final) [August 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of the phototoxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.Phototoxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Phototoxicity.KeyValueCsa
Results		Open list	ENDPOINT_SUMMARY.Phototoxicity.KeyValueCsa.Results
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: state 'not required' or 'not phototoxic/probably phototoxic/phototoxic'	Header 1	ENDPOINT_SUMMARY.Phototoxicity.Discussion

5.2.6 Phototoxicity – Endpoint Study record

Purpose:

The study shall provide information on the potential of certain active substances to induce cytotoxicity in combination with light, for example active substances that are phototoxic in vivo after systemic exposure and distribution to the skin, as well as active substances that act as photo-irritants after dermal application. A positive result shall be taken into account when considering potential human exposure. The in vitro study shall be required where the active substance absorbs electromagnetic radiation in the range 290- 700 nm and is liable to reach the eyes or light-exposed areas of skin, either by direct contact or through systemic distribution. If the Ultraviolet/visible molar extinction/absorption coefficient of the active substance is less than $10 \text{ L} \times \text{mol}^{-1} \times \text{cm}^{-1}$, no toxicity testing is required.

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ENDPOINT_STUDY_RECORD.PhototoxicityVitro - v.1.5 (Final) [October 2020]			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.DataSource
Materials and methods	<p>Material and methods – common block</p> <p>Type of study: Indicate whether an in vitro 3T3 NRU phototoxicity test or a reactive oxygen species (ROS) assay was performed.</p> <p>Applicable test guideline: OECD 432, OECD 101, Method B.41 In vitro 3T3 NRU phototoxicity test '.</p>	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestMaterials
Test system		Header 2	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem
Species / strain	Indicate the species and tester strain(s) used in the type of study indicated in the respective field above. Copy this field block for each tester strain.		ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.SpeciesStrain
Species / strain / cell type	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.SpeciesStrain.SpeciesStrainCell
Details on mammalian cell type (if applicable)	For robust study summaries, describe relevant details on cell cultures if applicable. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.SpeciesStrain.MammalianCellDetails

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Species / strain			
Controls	Indicate whether vehicle, true negative and/or positive controls were tested.		ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls
Negative solvent / vehicle controls	Indicate whether solvent / vehicle controls (i.e. consisting of solvent or vehicle alone, without test substance, and otherwise treated in the same way as the treatment groups) were tested. Any explanations can be given in the supplementary remarks field. In particular, indicate the concentration (and/or volume) of vehicle added.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls.NegativeControls
Positive controls	Indicate whether positive controls (i.e. substances with known genotoxicity) were tested. If so, indicate what substance(s) was/were used as positive control(s) in field "Positive control substance".	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls.PositiveControls
Positive control substance	<p>If applicable, indicate which substance(s) was/were used as positive control(s). Multiple items can be selected.</p> <p>If other than the reference substance(s) specified in the test guidelines was/were used, include a brief justification.</p> <p>Final concentration, conditions and durations of treatment and recovery periods.</p> <p>Note that the list of substances provided is not exhaustive.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls.PositiveControlSubstance
Remarks	Enter any remarks related to the recorded controls as appropriate.	Text	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls.Remarks
Controls			
Details on test system and experimental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.ExperimentalConditions
Vehicle	Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility. If yes, specify in field 'Details on test solution'.	Closed list	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndM

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		with remarks	ethods.TestSystem.Vehicle
Vehicle / solvent	<p>Indicate whether and which vehicle(s)/solvent(s) was/were used or state 'none' or 'no data' as applicable. Indicate if different vehicle/ solvent were used for tests with and without metabolic activation.</p> <p>Provide the percentage or volume of vehicle/solvent in the medium (e.g. 'DMSO (1% or 0.1 ml per 10 ml medium') and a justification for the choice of solvent/vehicle.</p> <p>Also indicate whether vehicle (or negative) controls (i.e. consisting of culture medium or medium with solvent or vehicle alone) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used.</p> <p>Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.</p>	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.VehicleSolvent
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive, negative or equivocal.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.EvaluationCriteria
Statistics	List parameters that were analysed and the statistical methods used; include a statement on the appropriateness of the statistical analyses used. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Statistics
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.KeyResult
Results	Include the main test results.	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.Results
Remarks on result	This field can be used for:	Open	ENDPOINT_STUDY_RECORD.Phototoxicity

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	<ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' 	list with remarks	yVitro.ResultsAndDiscussion.RemarksOnResult
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information.</p> <p>Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.ResultsReferenceSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.StatisticsErrorEstimates
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ApplicantSummaryAndConclusion

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5.2.7 Acute toxicity: other routes - Endpoint study record

<p>Purpose: Provide information:</p> <ul style="list-style-type: none"> - For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant. - For volatile active substances (vapour pressure >10⁻² Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes - v.7.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Species: NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.TestAnimals

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	reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.		
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Briefly describe details of exposure.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Doses	Include the doses including unit administered to the test animals, '5, 50, 500 and 2000 mg/kg bw'. As appropriate include notes in parentheses, e.g. '(male)'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether concurrent control group was used.	Open list with	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.Material

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		remarks	sAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the LD50 or other.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion
Effect levels	Provide the LD50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. If no LD50 or other endpoint available from picklist is reported, but only a dose level, specify this dose using 'other' and indicate the effects observed in subfield 'Remarks on result'.		ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.Sex

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Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 mg/kg bw or LD50 <10 mg/kg bw. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			

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Mortality	Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ApplicationSummaryAndConclusion
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5.3 Repeated dose toxicity – Endpoint summary

<p>Purpose:</p> <p>Chemical (Active): Provide consolidated information across the four routes (oral/inhalation/dermal/other) in both rodent and non-rodent species. The studies, data and information to be provided and evaluated, shall be sufficient to permit the identification of effects following repeated exposure to the active substance, and in particular to further establish, or indicate:</p> <ul style="list-style-type: none"> - Target organ / critical effect - Relevant oral reference point (e.g. NOAELs). - Relevant dermal reference point (e.g. NOAELs). - Relevant inhalation reference point (e.g. NOAELs). <p>Microorganisms (Active): In addition, an estimation of the microorganism clearance in the main organs must be performed. Investigations shall be included for pathogenicity and infectiveness endpoints.</p> <p>The document should contain the information needed to be reported according to the list of end points for short-term toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).</p>
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ENDPOINT_SUMMARY.RepeatedDoseToxicity - v.6.2 (Final) [August 2020]			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block Description of key information: Provide brief description of the toxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment
Toxic effect type	In this field, you should select whether there is a relationship between the exposure concentration and the	Closed list	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.ToxicEffectType

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	magnitude of the toxic effect, i.e. dose-dependent, or whether the toxic effect is driven but not modulated by the exposure concentration, i.e. concentration-driven.		
Repeated dose toxicity: via oral route - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRouteSystemicEffects
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>Study name / type: The study giving rise to the highest concern should be chosen e.g. most sensitive species. The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant. However, epidemiological studies should be reported under 5.9.4</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRouteSystemicEffects.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion: "Adverse effect observed" should be	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.Repeat

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	<p>chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg, µg/kg or mg/kg for the toxin(s) or CFU/kg bw or other relevant unit for the micro-organism.</p> <p>Study duration: The duration of the selected robust study summary.</p> <p>Species: The species reported in the selected</p>		<p>edDoseToxicityViaOralRouteSystemicEffects.EndpointConclusion</p>
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	<p>robust study summary should be chosen here.</p> <p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
Repeated dose toxicity: inhalation - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected:</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects.LinkToRelevantStudyRecords

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	quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP)		
Endpoint conclusion	<p>Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day.</p>	Header 3	ENDPOINT_SUMMARY. RepeatedDoseToxicity. KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects.EndpointConclusion

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	<p>Study duration: The duration of the selected robust study summary.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
<p>Repeated dose toxicity: inhalation - local effects</p>		<p>Header 2</p>	<p>ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects</p>

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<p>Link to relevant study records</p>	<p>Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.</p>	<p>Header 3</p>	<p>ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects.LinkToRelevantStudyRecords</p>
<p>Endpoint conclusion</p>	<p>Endpoint conclusion block (Species version) Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen. Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level).</p>	<p>Header 3</p>	<p>ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects.EndpointConclusion</p>

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	<p>The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. For the toxin(s) or CFU/kg bw or other relevant unit for the micro-organism. Study duration: The duration of the selected robust study summary.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern</p>		
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	should be selected, i.e. the system that is associated with the dose descriptor.		
Repeated dose toxicity: dermal - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP).</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects.LinkToRelevantStudyRecords
Endpoint conclusion	<p>Endpoint conclusion block (Species version)</p> <p>Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>"No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If "No study available" is chosen, a justification needs to be provided.</p> <p>If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects.EndpointConclusion

	<p>information necessary)” should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. For the toxin(s) or CFU/kg bw or other relevant unit for the micro-organism.</p> <p>Study duration: The duration of the selected robust study summary.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
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	<p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
Repeated dose toxicity: dermal - local effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP).</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.LinkToRelevantStudyRecords.Results
Endpoint conclusion	<p>Endpoint conclusion block (Species version)</p> <p>Endpoint conclusion: "Adverse effect"</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.Repeat

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	<p>observed” should be chosen if adverse effects were observed at or below the limit dose level. “No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level. If “No study available” is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), “No study available (further information necessary)” should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. Study duration: The duration of the selected robust study summary.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p>		<p>edDoseToxicityDermalLocalEffects.EndpointConclusion</p>
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	<p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY. RepeatedDoseToxicity. KeyValueForChemicalSafetyAssessment.ModeOfActionAnalysisHumanRelevanceFramework
	A discussion about the mode of action and the relevance of the data for human health should be provided here.	Rich text area	ENDPOINT_SUMMARY. RepeatedDoseToxicity. KeyValueForChemicalSafetyAssessment.ModeOfActionAnalysisHumanRelevanceFramework. ModeOfActionAnalysis
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY. RepeatedDoseToxicity. Discussion

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	Provide information on short-term toxicity studies in other species that the most sensitive species (described under study name / type, see above). Please provide: -Target organ/toxicity -Relevant dose descriptor (e.g. NOAEL)		
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.RepeatedDoseToxicity.JustificationForClassificationOrNonClassification.Remarks

5.3.1 Repeated dose toxicity: oral– Endpoint study record

<p>Purpose:</p> <p>Chemical (Active): Provide data related to the short-term oral toxicity of the active substance to rodents (90-day), usually the rat, a different rodent species shall be justified, and non rodents (90-day toxicity study in dogs), shall always be reported. Where available, 28-day studies shall be reported.</p> <p>Microorganism (Active): If the information already available is not sufficient to assess human health effects, data related to the short-term toxicity (minimum 28 days) of the microorganism must be reported, providing information on infectiveness, pathogenicity and toxicity. The choice of test species has to be justified. The choice of study length depends on acute toxicity and clearance data. Expert judgement is required to decide what route of administration is preferable.</p>

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral - v.8.4 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: 90 d OECD 408 OECD 409 Method B.26 Sub-chronic oral toxicity test. Method B.27 Sub-chronic oral toxicity test. 28 d OECD 407 Method B.7 Repeated dose (28 d).	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Details on route of administration	For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of the oral route and method of administration.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnRouteOfAdministration
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify. Further information can be	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxi

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	given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	with remarks	cityOral.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on oral exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnOralExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure

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Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

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Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference'	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency

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	and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.SacrificeAndPathology
Optional endpoint(s)	Describe any other optional endpoint(s).	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.OptionalEndpointS
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion

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Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	<p>Effect levels (OHT 67-69, 72-74) – common block</p> <p>Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.</p> <p>Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	<p>Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block</p> <p>Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.OverallRemarksAttachments
Applicant's summary and	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ApplicantSummaryAndConclusion

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conclusion			
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5.3.2 Repeated dose toxicity: inhalation – Endpoint study record

Purpose:

Chemical (Active): For volatile active substances (vapour pressure >10⁻² Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

Microorganism (Active): Information on the health effects after repeated inhalatory exposure is considered necessary, particularly for the risk assessment of the occupational setting. Repeated exposure might influence the clearance capacity (e.g. resistance) of the host (human). Furthermore, for proper risk assessment the toxicity after repeated exposure to contaminants, growth medium, co-formulants and the microorganism needs to be addressed. It should be kept in mind that the co-formulants in the plant protection product can influence the toxicity and infectiveness of the active.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation - v.8.5 (Final) [September 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Microbial Pesticide Test Guidelines: OPPTS 885.3600 Subchronic Toxicity/Pathogenicity Method B8 Repeated dose (28 days) toxicity (inhalation) (Annex to Regulation (EC) No 440/2008) Method B.29 Sub-chronic inhalation toxicity study 90-day repeated inhalation dose study using rodent species (Annex to Regulation (EC) No 440/2008) OECD Test Guideline 412: Subacute inhalation toxicity: 28-day study OECD Test Guideline 413: Subchronic inhalation toxicity: 90-day study	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods

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	Note that the OECD guidelines (and EC) are applicable to toxins if tested in isolation, while only OPPTS is applicable to the micro-organism.		
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.LimitTest
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity)	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure
Route of administration	Specify the route of administration by indicating in what physical form the test material was administered.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure	Indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield. In case of intratracheal administration, select other and report this in the 'remarks'	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposure
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter

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Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on inhalation exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnInhalationExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Close list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the difference between nominal and actual concentration was acceptable. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate total duration of exposure in days, weeks or months, e.g. '104 weeks', '90 days' or '28 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure

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Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., '6 hours/day, 7 days/week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, e.g. mg/L air (nominal), mg/L air (analytical), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to test group if different number of animals per group, e.g. '10 in each test group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

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Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency

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Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block For microorganisms, a verification that each enumeration method is sufficiently sensitive to serve as a useful quantitative assay for the micro-organism in tissues, organs, and body fluids should be reported	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion
Results of examinations	Results of examinations BLOCK (OHT: Repeated dose toxicity: oral) Details on results: For microorganisms, signs of infection and/or pathogenicity should be reported, as well as microbial enumeration from tissues, organs and body fluids (at different time points) to address infectivity and clearance estimate.	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxic

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	<p>quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.</p> <p>Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>		ityInhalation.ResultsAnd Discussion.EffectLevels
Target system / organ toxicity	<p>Target system BLOCK (OHT RepDoseTox etc.)</p> <p>Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAnd Discussion.TargetSystem OrganToxicity
Any other information on results incl. tables	<p>Any other information on results incl. tables Block</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAnd Discussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	<p>Overall remarks, attachments – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.OverallRemarksAttachments
Applicant's summary and conclusion	<p>Applicants summary and conclusion – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ApplicantSummaryAndConclusion

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5.3.3 Repeated dose toxicity: dermal – Endpoint study record

Optional: There is no data requirement for this endpoint, however the endpoint summary record presented below can be used if studies of this type are used to support the risk assessment

Purpose:

Chemical (Active): For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant.

Microorganism: There is no data requirement for this endpoint, however the endpoint study record presented below can be used if studies of this type are used to support the risk assessment

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal - v.7.5 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 411 (90 d) OECD 410 (28 d) Method B.9 Repeated dose (28 days) Method B.28 Sub-chronic dermal toxicity test: 90-day. Limit test: Indicate if the experiment was a limit test.	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity)	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure

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Type of coverage	Select type of coverage used. For robust study summaries or as requested by the regulatory programme, specify the area of application in field 'Details on dermal exposure'.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.TypeOfCoverage
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Close list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

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	also be included briefly explaining the rationale of referring to another study.		
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

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	the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference'	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency

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	and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion
Results of examinations	Results of examinations BLOCK (OHT: Repeated dose toxicity: oral) Body weight and weight changes: The effects should be also considered in relation to organ weights.	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.ResultsOfExaminations

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	Details on results: For micro-organisms, microbial enumeration in tissues, organs and body fluids (at different time points), and methods uses, and sensitivities and limits of detection (to address infectivity and clearance estimate) should be determined and reported.		
Effect levels	<p>Effect levels BLOCK (OHT 67-69, 72-74) Record the available effect levels for NO(A)EL(s), LO(A)EL(s) and other relevant dose descriptors. Copy this block of fields for entering different effect levels, based on different endpoints and/or separated for each sex.</p> <p>Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.EffectLevels
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.EffectLevels.Eff level.RemarksOnResults
Target system / organ toxicity	<p>Target system BLOCK (OHT RepDoseTox etc.) Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other informati	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDi

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on on results incl. tables			scussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ApplicantSummaryAndConclusion

5.3.4 Repeated dose toxicity: other routes – Endpoint study record

Purpose:

For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant.

For volatile active substances (vapour pressure >10⁻² Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther - v.7.4 (Final) [September 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.TestMaterial

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			ityOther.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Close list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate total duration of exposure in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., '8 hours/day, 7 days/week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExp

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			osure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to test group if different number of animals per group, e.g. '10 in each test group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMe

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		with remarks	thods.AdministrationExposure.ControlAnimals
Details on study design	<p>Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	<p>Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as</p>	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.SacrificeAndPathology

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	appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.EffectLevels

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	An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Target system / organ toxicity	<p>Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block</p> <p>Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystem

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			OrganToxicity.Treatment Related
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Close d list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Close d list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.RelevantForHumans
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.OverallRemarks Attachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ApplicantSummaryAndConclusion

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5.4 Genotoxicity testing - Endpoint summary

Purpose:

Chemical and Microorganism: State the available in vitro and in vivo studies and the results, as well the overall genotoxic potential. State the photomutagenicity potential, if required.

In the case of metabolites, it is recommended to complete datasets under section 1.4. Where available information on genotoxicity can come from additional sources such as QSAR and read-across there is the need to summarize and integrate all available evidence for genotoxicity in a summary table. For that purpose a template has been created. See IUCLID templates for PPP Risk Assessment - Template 5.3 - Template Summary table integrating experimental evidence on genotoxicity for metabolites. [<http://doi.org/10.5281/zenodo.4557333>].

The document should contain the information needed to be reported according to the list of end points for genotoxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

Microorganism: Test on toxins and relevant metabolites shall be performed using the purified chemical, if possible. Studies on the microorganism itself shall be considered depending on expert judgement.

ENDPOINT_SUMMARY.GeneticToxicity - v.5.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of the genotoxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.GeneticToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment
Genetic toxicity in vitro		Header 2	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected:	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro.LinkToRelevantStudyRecords

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	quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant.		
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (positive)" should be chosen if the outcome of the study was positive. "No adverse effect observed (negative)" should be chosen if the outcome of the study was negative. If "No study available" is chosen, a justification needs to be provided.	Closed list	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro.EndpointConclusion.EndpointConclusion
Genetic toxicity in vivo		Header 2	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo
Description of key information	Report Information to support the genetic toxicity in vivo.	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.DescriptionOfKeyInformation
		Rich text area	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.DescriptionOfKeyInformation.KeyInfo

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<p>Link to relevant study records</p>	<p>Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant.</p>	<p>Header 3</p>	<p>ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.LinkToRelevantStudyRecords</p>
<p>Endpoint conclusion</p>		<p>Header 3</p>	<p>ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.EndpointConclusion</p>
<p>Endpoint conclusion</p>	<p>“Adverse effect observed (positive)” should be chosen if the outcome of the study was positive. “No adverse effect observed (negative)” should be chosen if the outcome of the study was negative. If “No study available” is chosen, a justification needs to be provided. If the dossier contains a testing proposal for genetic toxicity in vivo, “No study available (further information necessary)” should be chosen.</p>	<p>Closed list</p>	<p>ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.EndpointConclusion.EndpointConclusion</p>
<p>Mode of Action Analysis / Human</p>		<p>Header 2</p>	<p>ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAss</p>

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Relevance Framework	<p>This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats. The template is also available in HTML format that can be easily uploaded in this textarea where relevant</p>	Rich text area	<p>essment.MoAHumanRelevanceFramework ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.MoAHumanRelevanceFramework.MoAHumanRelevanceFramework</p>
Additional information	<p>Discussion (Header 1) – common block Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - In vitro studies (state the available in vitro studies and the results), - In vivo studies (state the available in vivo studies and the results) <p>Provide a statement on the photomutagenicity potential: e.g.</p> <ul style="list-style-type: none"> -Not required -Unlikely to be photomutagenic <p>Attached background material: Provide the original version of any document that contains confidential material.</p>	Header 1	<p>ENDPOINT_SUMMARY.GeneticToxicity.Discussion</p>

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	<p>For metabolites, please attach the summary table integrating available evidence for genotoxicity on metabolites. See IUCLID templates for PPP Risk Assessment or PPP IUCLID Templates - Template 5.3. Summary table integrating experimental evidence on genotoxicity for metabolites. [http://doi.org/10.5281/zenodo.4557353]</p>		
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.GeneticToxicity.JustificationForClassificationOrNonClassification
	<p>The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.</p>	Rich text area	ENDPOINT_SUMMARY.GeneticToxicity.JustificationForClassificationOrNonClassification.Remarks

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5.4.1 In vitro studies – Endpoint study record

Purpose:

Chemical (Active): The following in vitro mutagenicity tests shall be performed: bacterial assay for gene mutation, combined test for structural and numerical chromosome aberrations in mammalian cells and test for gene mutation in mammalian cells. However, if gene mutation and clastogenicity/aneuploidy are detected in a battery of tests consisting of Ames and in vitro micronucleus (IVM), no further in vitro testing needs to be conducted. If there are indications of micronucleus formation in an in vitro micronucleus assay further testing with appropriate staining procedures shall be conducted to clarify if there is an aneugenic or clastogenic response. Further investigation of the aneugenic response may be considered to determine whether there is sufficient evidence for a threshold mechanism and threshold concentration for the aneugenic response (particularly for non-disjunction). Active substances which display highly bacteriostatic properties as demonstrated in a range finding test shall be tested in two different in vitro mammalian cell tests for gene mutation. Non performance of the Ames test shall be justified. For active substances bearing structural alerts that have given negative results in the standard test battery, additional testing may be required if the standard tests have not been optimised for these alerts. The choice of additional study or study plan modifications depends on the chemical nature, the known reactivity and the metabolism data on the structurally alerting active substance.

Microorganism (Active): If the microorganism produces secondary metabolites/toxins, then these compounds and any other relevant metabolites in the culture medium must also be tested for genotoxicity. Such tests shall be performed using the purified chemical if possible.

If basic studies do not indicate that toxic metabolites are formed, studies on the microorganism itself shall be considered depending on expert judgement on the relevance and validity of the basic data. In the case of a virus the risk of insertional mutagenesis in mammal cells or the risk of carcinogenicity has to be discussed.

ENDPOINT_STUDY_RECORD.GeneticToxicityVitro - v.9.5 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.Administrative Data
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.13/14 Mutagenicity - reverse mutation test using bacteria Method B.10 Mutagenicity - In vitro mammalian chromosome aberration test Method B.17 – Mutagenicity – In vitro mammalian cell gene mutation test OECD 471	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods

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	OECD 473 OECD 476 OECD 487		
Type of assay	As appropriate supplement the information provided in field 'Endpoint' and indicate the type of assay used.	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.TypeOfAssay
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method
Target gene	Indicate the target gene (HPRT, XPRT, TK, ATPase, other: specify) only if necessary to characterise the test system.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.TargetGene
Species / strain	Indicate the species and tester strain(s) used in the type of study indicated in the respective field above. Copy this field block for each tester strain.		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain
Species / strain / cell type	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain.SpeciesStrain
Details on mammalian cell type (if applicable)	For robust study summaries, describe relevant details on cell cultures if applicable. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain.DetailsOnMammalianCellLinesIfApplicable
Additional strain / cell type characteristics	For robust study summaries, indicate additional strain characteristics (e.g. 'DNA-Polymerase-A-deficient') only if necessary to characterise the test system. Otherwise, leave this subfield empty.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain.AdditionalStrainCharacteristics
Species / strain			

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Cytokine block (if used)	If a cytokinesis blocking substance (e.g. cytoB) was used, indicate its identity and its concentration and duration of cell exposure.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.CytokinesisBlockIfUsed
Metabolic activation	Indicate whether metabolic activation was applied or not. Select 'not applicable' for mammalian cell lines when no exogenous metabolic system is required.	Close list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.MetabolicActivation
Metabolic activation system	For robust study summaries, specify metabolic activation system, if any. Indicate the type and composition of and acceptability criteria for the metabolic activation system used. Alternatively or in addition refer to appropriate table(s), which can be uploaded in the rich text field "Any other information on materials and methods incl. tables". Use predefined table or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.MetabolicActivationSystem
Test concentrations with justification for top dose	Indicate the test concentrations without and with metabolic activation, and for the different treatment harvest schedules. For robust study summaries or as requested by the regulatory programme, include a justification for the maximum dose level used, for instance if maximum recommended concentration for the test, limited by solubility (in solvent and/or culture medium, and presence of precipitates) or cytotoxicity indicating the parameter measured and the targeted level of cytotoxicity, and a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.TestConcentrationsWithJustificationForTopDose
Vehicle / solvent	Indicate whether and which vehicle(s)/solvent(s) was/were used or state 'none' or 'no data' as applicable. Indicate if different vehicle/ solvent were used for tests with and without metabolic activation. Provide the percentage or volume of vehicle/solvent in the medium (e.g. 'DMSO (1% or 0.1 ml per 10 ml medium)') and a justification for the choice of solvent/vehicle. Also indicate whether vehicle (or negative) controls (i.e. consisting of culture medium or medium with solvent or	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Vehicle

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	vehicle alone) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used. Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.		
Controls	Indicate whether vehicle, true negative and/or positive controls were tested. Repeat this block of fields as necessary, particularly if controls or different substances were used for tests with and without metabolic activation or cytokinesis block. If necessary, indicate so in the supplementary remarks field or in subfield 'Remarks'.		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls
Untreated negative controls	Indicate whether untreated negative controls (i.e. consisting of culture medium without solvent / vehicle or test substance, and otherwise treated in the same way as the treatment groups) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used . Any explanations can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.NegativeControls
Negative solvent / vehicle controls	Indicate whether solvent / vehicle controls (i.e. consisting of solvent or vehicle alone, without test substance, and otherwise treated in the same way as the treatment groups) were tested. Any explanations can be given in the supplementary remarks field. In particular, indicate the concentration (and/or volume) of vehicle added.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.SolventControls
True negative controls	Indicate whether true negative control(s) (i.e. substances with known lack of genotoxicity) was/were tested and specify the substance(s) and concentration (and/or volume) in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.TrueNegativeControls
Positive controls	Indicate whether positive controls (i.e. substances with known genotoxicity) were tested. If so, indicate what substance(s) was/were used as positive control(s) in field "Positive control substance".	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.PositiveControls
Positive control substance	If applicable, indicate which substance(s) was/were used as positive control(s). Multiple items can be selected. If different substances were used for tests with and without metabolic activation or for different tester strains or for the different treatment harvest schedules, include a remark in subfield 'Remarks'. If other than the reference substance(s) specified in the test guidelines was/were used, include a brief	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.PositiveControlSubstance

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	justification. Final concentration, conditions and durations of treatment and recovery periods. Note that the list of substances provided is not exhaustive.		
Remarks	Enter any remarks related to the recorded controls as appropriate.	Text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.Remarks
Controls			
Details on test system and experimental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.DetailsOnTestSystemAndConditions
Rationale for test conditions	Provide the rationale for selection of concentrations and number of cultures, including cytotoxicity data and solubility limitations, if available.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.RationaleForTestConditions
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive, negative or equivocal.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.EvaluationCriteria
Statistics	List parameters that were analysed and the statistical methods used; include a statement on the appropriateness of the statistical analyses used. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and		Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicity

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discussion			yVitro.ResultsAndDiscussion
Test results	<p>Include the main test results in this block of fields for each tester strain and metabolic activation system used. Multiply this block of fields as often as required. (Note: If only one strain was tested, subfield 'Species/strain' may be left empty.)</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the relevant raw data including statistical analysis and p-values if any, in field 'Additional information on results' and/or refer to detailed tables on the genotoxicity and cytotoxicity results, which can be uploaded in the rich text field 'Any other information on results incl. tables'. Use table numbers in the sequence in which you refer to them (e.g. '... see Table 1'). For instance, results for each strain ± metabolic activation (e.g. S9 mix) in an Ames test should be tabulated.</p>		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.KeyResult
Species / strain	Indicate the species/strain or cell type tested. Multiply this block of fields for each tester strain.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.Organism
Metabolic activation	Indicate whether metabolic activation was applied or not.	Close d list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.MetActIndicator
Genotoxicity	<p>Indicate result of the test conducted with the tester strain(s), or cell types and the metabolic activation system specified. If positive or equivocal, include concentration(s) in the supplementary remarks field or representative table. Upload predefined or other appropriate table(s) if any in the rich text field 'Any other information on results incl. tables' and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.Genotoxicity
Cytotoxicity /	Indicate whether cytotoxicity was observed. If yes, specify the respective test concentration(s) in the	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicity

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choice of top concentrations	supplementary remarks field and provide details on the cytotoxicity measurement. Alternatively or in addition, use the field 'Any other information on results incl. tables'. If you refer to table(s), use appropriate table numbers (e.g. '... see Table 1'). Note: Specific tables may be required.	with remarks	yVitro.ResultsAndDiscussion.TestRs.Cytotoxicity
Vehicle controls validity	Indicate whether test with vehicle control(s) (i.e. vehicle without test substance,) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.VehContrValid
Untreated negative controls validity	Indicate whether test with untreated controls, if applicable (i.e. no vehicle and no test substance) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.NegContrValid
True negative controls validity	Indicate whether test with true negative control(s) (i.e. substances with known lack of genotoxicity) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.TrueNegativeControlsValidity
Positive controls validity	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.PosContrValid
Test results			
Additional information on results	Enter any additional information that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.ResultsDetails
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.RemarksOnResults
Any other information on results	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.AnyOtherInfor

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incl. tables			mationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ApplicantSummaryAndConclusion

5.4.2 In vivo studies – Endpoint study record

<p>Purpose: If all the results of the in vitro studies are negative, at least one in vivo study shall be done with demonstration of exposure to the test tissue (such as cell toxicity or toxicokinetic data), unless valid in vivo micronucleus data are generated within a repeat dose study and the in vivo micronucleus test is the appropriate test to be conducted to address this information requirement.</p>
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ENDPOINT_STUDY_RECORD.GeneticToxicityVivo - v.8.4 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.12 - Mutagenicity - In vivo mammalian erythrocyte micronucleus test Method B.11 - Mutagenicity – In vivo mammalian bone-marrow chromosome aberration test OECD 474 OECD 475 OECD 486 OECD 488 Method B.39 Unscheduled DNA synthesis (UDS) - Test with mammalian liver cells in vivo In vivo Comet assay.	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods

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Type of assay	As appropriate supplement the information provided in field 'Endpoint' and indicate the type of assay used.	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Studytype
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity)	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure
Route of administration	Select route of administration as appropriate, usually 'oral: gavage'. If another route was used, provide a justification and reasoning in field 'Details on exposure'. In the case of an inhalation study, also specify if 'nose only' or other.	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Indicate whether vehicle(s)/solvent(s) was/were used and specify the substance(s) or state 'none' if no vehicle/solvent was used or 'no data' if not available from the study report or publication. Provide a justification for the choice of solvent/vehicle. Provide further details as appropriate. Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DetailsonExposure
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '5 days' or '10 weeks'.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.Durat

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			ionOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'once' or 'daily injections' or '2 doses per day, 7 days per week').	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.PostExposurePeriod
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DoseConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DoseConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DoseConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify if different number of animals were used per sex and/or dose level or for the pilot, range-finding and main study. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.NoOf

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	information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		AnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.ControlGroup
Positive control(s)	Indicate what substance(s) was/were used as positive control(s) or state 'none' if no positive controls were used or 'no data' if not available from the study report or publication. If other than the reference substance(s) specified in the test guidelines was/were used include a brief justification. Also provide information on the route of administration and doses either under separate headings or in parentheses after the control substance(s) specified. Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.PositiveControls
Examinations		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations
Tissues and cell types examined	Indicate tissues and cell types examined including the number of cells analysed per animal. Also note if examinations were not performed with tissues or cells from all animals studied. For robust study summaries or as requested by the regulatory programme, also include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.TissuesAndCellTypesExamined
Details of tissue and slide preparation	Indicate any relevant details to characterise the test system and test protocol used. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.DetailsOfTissueAndSlidePreparation

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Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.EvaluationCriteria
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion
Test results	Include the main test results in this block of fields. Multiply this block of fields as often as required, e.g. for recording different results for both sexes used. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the genotoxicity and toxicity results in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs
Key result	This read-only field displays the key results flagged in the corresponding results table(s), if any.	Checkbox	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.KeyResult
Sex	Select from drop-down list.	Close d list	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.Sex
Genotoxicity	Indicate if there was evidence of genotoxicity. If result is considered positive or ambiguous, include dose(s) in the	Open list	ENDPOINT_STUDY_RECORD.GeneticTox

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	supplementary remarks field or representative table, e.g. predefined table or an excerpt from the study report.	with remarks	icityVivo.ResultsAnd Discussion.TestRs.Genotoxicity
Toxicity	Indicate whether signs of toxicity were observed or not. If yes, briefly describe the in life animal observations and the effects by dose in the supplementary remarks field (e.g. 'significantly decreased body weight gain in the high dose group'). If necessary include further details in field 'Additional information on results'.	Close list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAnd Discussion.TestRs.Toxicity
Vehicle controls validity	Indicate whether test with vehicle control(s) (i.e. without test substance, with/without solvent) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAnd Discussion.TestRs.VehContrValid
Negative controls validity	Indicate whether test with true negative control(s) (i.e. substances with known lack of genotoxicity) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAnd Discussion.TestRs.NegContrValid
Positive controls validity	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAnd Discussion.TestRs.PosContrValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAnd Discussion.TestRs.RemarksOnResults
Test results			
Additional information on results	Briefly describe the results of results of range-finding study if any. For the definitive study, provide further details on results. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Particularly with comprehensive data, include a table and refer to respective table no. (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAnd Discussion.ResultsDetails

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	Note: Depending on the regulatory programme some form of a table may be mandatory.		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ApplicantSummaryAndConclusion

5.5 Carcinogenicity – Endpoint summary

Purpose:

Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details for both rat and mice species:

- Long-term effects (target organ/critical effect)
- Relevant reference points (e.g. NOAELs) for long-term toxicity.
- Carcinogenicity (target organ, tumour type)
- Relevant reference points (e.g. NOAELs) for carcinogenicity

The document should contain the information needed to be reported according to the list of end points for long-term toxicity and carcinogenicity (SANCO/12592/2012-rev. 2, 22 March 2019).

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP - v.5.0 (Final) [July 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of carcinogenicity studies and effects.	Header 1	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP

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			P.KeyValueForChemical SafetyAssessment
Long-term toxicity: via oral route		Header 2	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.KeyValueForChemical SafetyAssessment.Long TermToxOral
Link to relevant study records		Header 3	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.KeyValueForChemical SafetyAssessment.Long TermToxOral.RelevantRecords
Study name / type	<p>The study giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP).</p> <p>Available epidemiological data are preferred provided that they are reliable and relevant. However, epidemiological studies should be reported under 5.9.4</p>	Endpoint reference list	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.KeyValueForChemical SafetyAssessment.Long TermToxOral.RelevantRecords.StudyNameType
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>Multiple species can be reported, e.g.: two species, rat and mouse should be reported for pesticides.</p>		ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.KeyValueForChemical SafetyAssessment.Long TermToxOral.RelevantRecords.EndpointConclusion

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	<p>Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>"No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If "no study available" is chosen, a justification needs to be provided.</p> <p>If the dossier contains a testing proposal for repeated dose toxicity (e.g. 2-year study), "no study available (further information necessary)" should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level).</p> <p>The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg, µg/kg or mg/kg.</p> <p>Study duration: Choose the duration of the</p>		
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	<p>selected robust study summary: i.e. chronic.</p> <p>Experimental exposure time per week (hours/week): In this field, you should add the experimental exposure conditions in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>System: The systems in which adverse effects were observed should be specified here.</p> <p>Organ: The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
Endpoint conclusion			
Carcinogenicity: via oral route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaOralRoute

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<p>Link to relevant study records</p>	<p>The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.</p>	<p>Header 3</p>	<p>ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaOralRoute.LinkToRelevantStudyRecords</p>
<p>Endpoint conclusion</p>	<p>Endpoint conclusion (Species version) – common block</p> <p>Multiple species can be reported, e.g.: two species, rat and mouse should be reported for pesticides.</p> <p>Endpoint conclusion: “Adverse effect observed” should be chosen if the substance was found to be carcinogenic. “No adverse effect observed” should be chosen if the substance was not found to be carcinogenic in the available study(ies). If “No study available” is chosen, a justification needs to be provided. If the dossier contains a testing proposal for carcinogenicity “No study available (further information necessary)” should be chosen.</p> <p>Dose descriptor: The selection of the dose descriptor should only</p>		<p>ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaOralRoute.LinkToRelevantStudyRecords.EndpointConclusion</p>

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	<p>refer to carcinogenic effects.</p> <p>Study duration: Choose the duration of the selected robust study summary. Most of the in vivo carcinogenicity studies are chronic studies.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>System: The systems in which cancer was observed should be specified here.</p> <p>Organ: The organ in which cancer was observed should be specified here. If cancer was observed in several organs, the target organ in which the adverse effects gives rise to highest concern should be selected, i.e. the organ that is associated with the dose descriptor.</p>		
Endpoint conclusion			
Carcinogenicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaInhalationRoute
Link to relevant study records	The following factors, among others, should be taken into account when the robust study summary is selected:	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaInhalation

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	quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.		Route.LinkToRelevantStudyRecords
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>Endpoint conclusion: “Adverse effect observed” should be chosen if the substance was found to be carcinogenic. “No adverse effect observed” should be chosen if the substance was not found to be carcinogenic in the available study(ies). If “No study available” is chosen, a justification needs to be provided. If the dossier contains a testing proposal for carcinogenicity “No study available (further information necessary)” should be chosen</p> <p>Dose descriptor: The selection of the dose descriptor should only refer to carcinogenic effects.</p> <p>Study duration: Choose the duration of the selected robust study summary. Most of the in vivo carcinogenicity studies are chronic studies.</p> <p>Species: The species reported in the selected</p>	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaInhalationRoute.EndpointConclusion

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	<p>robust study summary should be chosen here</p> <p>System: The system in which cancer was observed should be specified here. If cancer was observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>Organ: The organ in which cancer was observed should be specified here. If cancer was observed in several organs, the target organ in which the adverse effects gives rise to highest concern should be selected, i.e. the organ that is associated with the dose descriptor.</p>		
Carcinogenicity: via dermal route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaDermalRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaDermalRoute.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP

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			P.KeyValueForChemical SafetyAssessment.CarcinogenicityViaDermalRoute.LinkToRelevantStudyRecords.Results
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>Endpoint conclusion: “Adverse effect observed” should be chosen if the substance was found to be carcinogenic. “No adverse effect observed” should be chosen if the substance was not found to be carcinogenic in the available study(ies). If “No study available” is chosen, a justification needs to be provided. If the dossier contains a testing proposal for carcinogenicity “No study available (further information necessary)” should be chosen.</p> <p>Dose descriptor: The selection of the dose descriptor should only refer to carcinogenic effects.</p> <p>Study duration: Choose the duration of the selected robust study summary. Most of the in vivo carcinogenicity studies are chronic studies.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p>	Header 3	<p>ENDPOINT_SUMMARY.Carcinogenicity_EU_PP</p> <p>P.KeyValueForChemical SafetyAssessment.CarcinogenicityViaDermalRoute.EndpointConclusion</p>

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	<p>System: The system in which cancer was observed should be specified here. If cancer was observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor</p> <p>Organ: The organ in which cancer was observed should be specified here. If cancer was observed in several organs, the target organ in which the adverse effects gives rise to highest concern should be selected, i.e. the organ that is associated with the dose descriptor</p>		
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.KeyValueForChemical SafetyAssessment.MoA HumanRelevanceFramework
	<p>This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats . The template is also available in HTML</p>	Rich text area	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.KeyValueForChemical SafetyAssessment.MoA HumanRelevanceFramework.MoAHumanRelevanceFramework

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	format that can be easily uploaded in this text area where relevant		
Additional information	<p>Discussion(Header 1) – common block</p> <p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> -Further description of the critical effects/target organ for long-term toxicity, such as direction of the critical effect: e.g. increased liver weight in rats. -Further description of the critical effects/target organ for carcinogenicity, such as tumour type: e.g. adenocarcinoma in rats 	Header 1	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.JustificationForClassificationOrNonClassification.JustifClassifCarc

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5.5 Carcinogenicity – Endpoint study record

Purpose:

The results of the long-term studies conducted and reported, taken together with other relevant data and information on the active substance, shall be sufficient to permit the identification of effects, following repeated exposure to the active substance, and in particular shall be sufficient to:

- identify adverse effects resulting from long-term exposure to the active substance,
- identify target organs, where relevant,
- establish the dose-response relationship,
- establish the reference point (e.g. NOAELs) and, if necessary, other appropriate reference points.

Correspondingly, the results of the carcinogenicity studies taken together with other relevant data and information on the active substance, shall be sufficient to permit the evaluation of hazards for humans, following repeated exposure to the active substance, and in particular shall be sufficient: (a) to identify carcinogenic effects resulting from long-term exposure to the active substance; 3.4.2013 Official Journal of the European Union L 93/27 EN (b) to establish the species, sex, and organ specificity of tumours induced; (c) to establish the dose-response relationship; (d) where possible, to identify the maximum dose eliciting no carcinogenic effect; (e) where possible, to determine the mode of action and human relevance of any identified carcinogenic response.

ENDPOINT_STUDY_RECORD.Carcinogenicity - v.7.5 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: <ul style="list-style-type: none"> - Method B.32 Carcinogenicity test (Annex to Regulation (EC) No 440/2008). - Method B.33 Combined chronic toxicity/carcinogenicity test (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 451: Carcinogenicity Studies. - OECD Test Guideline 453: Combined Chronic Toxicity/Carcinogenicity Studies. - other 	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.

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			MaterialsAndMethods. TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure
Route of administration	Select route of administration as appropriate, usually 'oral: gavage'. If another route was used, provide a justification and reasoning in field 'Details on exposure'. In the case of an inhalation study, also specify if 'nose only' or other.	Open list	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.TypeOfInhalationExposureIfApplicable
Vehicle	Select the vehicle used. If not available from picklist, select 'other'. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.Remarks
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study	Text template	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods.

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	summary or that are requested by the respective regulatory programme.		AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Close list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	<p>For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.</p> <p>Further route-dependent information to be included:</p> <ul style="list-style-type: none"> - For oral studies: State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis.It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable. 	Text area	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

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Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '18 months'.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material. Specify, if there are differences for treatment and recovery groups or other individual groups.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.PostExposurePeriod
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet, mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure

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	<p>group if applicable.</p> <p>For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>		e.NoOfAnimalsPerSexPerDose
Control animals	<p>Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	<p>Include any details on the study design including toxicokinetic data if available, a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	<p>Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.Examinations

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Observations and examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. Examinations.Observat ionsAndExaminationsP erformedAndFrequenc y
Sacrifice and pathology	<p>Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. Examinations.Sacrifice AndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. Examinations.OtherExa minations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. Examinations.Statistics
Any other information on	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. AnyOtherInformationO

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materials and methods incl. tables			nMaterialsAndMethods InclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity. ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity. ResultsAndDiscussion. ResultsOfExaminations
Relevance of carcinogenic effects / potential	Discuss carcinogenic effects / potential, i.e. state if there was (not) a treatment related increase in tumour incidence as compared to controls and specify tumour type if applicable. Indicate if dosing was not considered adequate. Discuss weight of evidence with respect to relevance of tumours observed for human health. This should be in line with information entered under 'Target system / organ toxicity'. Discuss conclusions given in supporting documentation.	Text area	ENDPOINT_STUDY_RECORD.Carcinogenicity. ResultsAndDiscussion. ResultsOfExaminations .RelevanceOfCarcinogenicEffectsPotential
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity. ResultsAndDiscussion. EffectLevels
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity. ResultsAndDiscussion. TargetSystemOrganToxicity

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Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.ApplicantSummaryAndConclusion

5.6 Reproductive toxicity (includes reproduction toxicity to mammals) – Endpoint summary

Purpose:

Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details:

Reproduction toxicity

- Reproduction target / critical effect for parental, reproductive and offspring
- Relevant parental reference point (e.g. NOAELs).
- Relevant reproductive reference point (e.g. NOAELs).
- Relevant offspring reference point (e.g. NOAELs).

Developmental toxicity (rats and rabbits)

- Developmental target / critical effect
- Relevant maternal reference point (e.g. NOAELs).
- Relevant developmental reference point (e.g. NOAELs).

The document should contain the information needed to be reported according to the list of end points for reproductive toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP - v1.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction

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	Provide a brief description of reproductive toxicity studies and effects.		_EU_PPP.Administrative DataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment
Toxic effect type	In this field, you should select whether there is a relationship between the exposure concentration and the magnitude of the toxic effect, i.e. dose-dependent, or whether the toxic effect is driven but not modulated by the exposure concentration, i.e. concentration-driven.	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicEffectType
Effects on reproductive toxicity / fertility		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.LinkToRelevantStudyRecords
Effect on fertility-reproductive toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute
Endpoint conclusion	Endpoint conclusion (Species version) – common block	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment

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	<p>“Adverse effect observed” should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on “reproductive toxicity”.</p> <p>The study duration of the selected robust study summary should be amongst: Two-generation studies (OECD 416) or extended one-generation studies (OECD 443). Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as “subacute” studies or as “developmental” studies (e.g. for pesticides).</p>		<p>nt.EffectsOnFertility.EffectOnFertilityViaOralRoute.EndpointConclusion</p>
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	<p>Experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species should be reported in the relative field.</p>		
Basis for effect level	<p>Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.</p>	<p>Multi select open list with remarks (32000)</p>	<p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.BasisForEffectLevel</p>
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or 	<p>Open list with remarks (2000)</p>	<p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.RemarksOnResult</p>

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	- entering any additional information on the effect level by selecting 'other:'.		
Species	The species reported in the selected robust study summary should be chosen here.	Open list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.Species
Effect on fertility-parental toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>The dose descriptor should only refer for</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute.EndpointConclusion

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	<p>the specific effect on "parental toxicity".</p> <p>The duration of the selected robust study summary, should be: Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as "subchronic" studies or as "multigeneration" studies (e.g. for pesticides). Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies or as "developmental" studies (e.g. for pesticides).</p> <p>The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species should be reported in the relative field, usually the rat.</p>		
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY. ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.Eff

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	pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.		ectOnParentalToxViaOralRoute.BasisForEffectLevel
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute.RemarksOnResult
Effect on fertility-offspring toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringT

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	<p>reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on “offspring toxicity”.</p> <p>The duration of the selected robust study summary.</p> <p>Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as “subchronic” studies or as “multigeneration” studies (e.g. for pesticides).</p> <p>Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as “subacute” studies or as “developmental”</p>		<p>oxOralRoute.EndpointConclusion</p>
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	<p>studies (e.g. for pesticides). The experimental exposure conditions should be added in hours per week. This can be done considering the hours per day and the days per week the animals were exposed</p> <p>The species reported in the selected robust study summary should be chosen in the relative field, usually the rat.</p>		
Basis for effect level	<p>Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.</p>	<p>Multi select open list with remarks (32000)</p>	<p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute.BasisForEffectLevel</p>
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and 	<p>Open list with remarks (2000)</p>	<p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute.RemarksOnResult</p>

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	<p>entering free text explanation in the supplementary remarks field; or</p> <p>- entering any additional information on the effect level by selecting 'other:'.</p>		
Effect on fertility: via inhalation route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaInhalationRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaInhalationRoute.EndpointConclusion

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	<p>toxicity) and dose descriptors should be reported in the section "Description of key information.</p> <p>The duration of the selected robust study summary.</p> <p>Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as "subchronic" studies.</p> <p>Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies.</p> <p>The experimental exposure conditions should be added in hours per week. This can be done considering the hours per day and the days per week the animals were exposed</p> <p>The species reported in the selected robust study summary should be chosen in the relative field, usually the rat.</p>		
<p>Effect on fertility: via dermal route</p>		<p>Header 3</p>	<p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.Eff</p>

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			ectOnFertilityViaDermal Route
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be reported in the section “Description of key information”.</p> <p>The duration of the selected robust study summary, should be: Two-generation studies (OECD 416) and extended one-generation studies (OECD 443) are to be</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaDermalRoute.EndpointConclusion

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	<p>reported as "subchronic" studies. Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies.</p> <p>The experimental exposure conditions should be added in hours per week. This can be done considering the hours per day and the days per week the animals were exposed</p> <p>The species reported in the selected robust study summary should be chosen in the relative field.</p>		
Additional information		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.AdditionalInformation
	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the 	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.AdditionalInformation.AdditionalInfo

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	<p>endpoint</p> <ul style="list-style-type: none"> - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>		
Effects on developmental toxicity		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity
Description of key information	Report Information to support the developmental toxicity.	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.DescriptionOfKeyInformation
		Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.DescriptionOfKeyInformation.KeyInfo
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.LinkToRelevantStudyRecords
Effect on developmental		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForC

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toxicity: via oral route			hemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute
Developmental toxicity	According to EU data requirements on pesticides at least two developmental toxicity studies should be available, one in rat and one in rabbits. The two species should be reported.		ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicityViaOralRoute.DevTox
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse developmental effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse developmental effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>If the dossier contains a testing proposal for developmental toxicity, “no study available (further information necessary)” should be chosen.</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicityViaOralRoute.DevTox.EndpointConclusion

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	<p>The selection of the dose descriptor should only refer for specific effect on maternal toxicity.</p> <p>The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies</p> <p>The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.</p>		
Basis for effect level	<p>Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.</p>	<p>Multi select open list with remarks (32000)</p>	<p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox.BasisForEffectLevel</p>

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Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox.RemarksOnResult
Developmental toxicity			
Effect on developmental toxicity - maternal: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal
Maternal toxicity	<p>According to EU data requirements on pesticides at least two developmental toxicity studies should be available, one in rat and one in rabbits. The two species should be reported.</p>		ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment

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	<p>“Adverse effect observed” should be chosen if adverse developmental effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse developmental effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>If the dossier contains a testing proposal for developmental toxicity, “no study available (further information necessary)” should be chosen.</p> <p>The selection of the dose descriptor should only refer for the specific effect on developmental toxicity.</p> <p>The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as “subacute” studies.</p> <p>The experimental exposure conditions</p>		<p>nt.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity.EndpointConclusion</p>
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	<p>should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.</p>		
Basis for effect level	<p>Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.</p>	<p>Multi select open list with remarks (32000)</p>	<p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity.BasisForEffectLevel</p>
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or 	<p>Open list with remarks (2000)</p>	<p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity.RemarksOnResult</p>

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	- entering any additional information on the effect level by selecting 'other:'.		
Maternal toxicity			
Effect on developmental toxicity: via inhalation route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaInhalationRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be reported in the section</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaInhalationRoute.EndpointConclusion

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	<p>"Description of key information".</p> <p>The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies.</p> <p>The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.</p>		
Effect on developmental toxicity: via dermal route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaDermalRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>"Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaDermalRoute.EndpointConclusion

	<p>level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be reported in the section "Description of key information".</p> <p>The duration of the selected robust study summary should be: Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as "subchronic" studies. Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies.</p> <p>The experimental exposure conditions should be reported in</p>		
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	<p>hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species reported in the selected robust study summary should be chosen in the relative field.</p>		
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.AdditionalInformation
	<p>Provide any additional information related to the endpoint.</p>	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopme

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			ntalToxicity.AdditionalInformation.AdditionalInfo
Toxicity to reproduction: other studies		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies
Description of key information	Report Information to support the toxicity on reproduction.	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies.DescriptionOfKeyInformation
		Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies.DescriptionOfKeyInformation.KeyInfo
Link to relevant study records	If other studies relevant to toxicity to reproduction are available should be reported here. The specifics should be reported in the section "Description of key information".	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies.LinkToRelevantStudyRecords
Additional information	Provide additional information related to the endpoint, for example: <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value 	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies.AdditionalInformation

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	<p>that characterises the endpoint</p> <ul style="list-style-type: none"> - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>		
		Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOtherStudies.AdditionalInformation.AdditionalInfo
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework
	<p>This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats . The template is also available in HTML format that can be easily uploaded in this</p>	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework.MoAAAnalysisHumanRelevanceFramework

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	text area where relevant		
Additional information	<p>Discussion(Header 1) – common block</p> <p>If available, for other routes than oral provide additional information related to the endpoint, for example: Reproduction target / critical effect, Relevant parental reference point (e.g. NOAELs), Relevant reproductive reference point (e.g. NOAELs), Relevant offspring reference point (e.g. NOAELs), If there is no additional information to be reported this field may be left empty.</p>	Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.JustificationForClassificationOrNonClassification.JustificationForClassificationOrNonClassification

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5.6 Reproductive toxicity (includes reproduction toxicity to mammals) – Endpoint study record

Purpose:

Possible effects on reproductive physiology and the development of progeny shall be investigated and reported concerning the following aspects:

- Impairment of male and female reproductive functions or capacity, for example from effects on oestrus cycle, sexual behaviour, any aspect of spermatogenesis or oogenesis, or hormonal activity or physiological response which would interfere with the capacity to fertilise, fertilisation itself or development of the fertilised ovum up to and including implantation.
- Harmful effects on the progeny, for example any effect interfering with normal development, both before and after birth. This includes morphological malformations such as anogenital distance, nipple retention, and functional disturbances (such as reproductive and neurological effects).

Multigeneration studies (e.g. two-generation toxicity study and/or 1-extended one generation study) should be reported using this endpoint study record.

ENDPOINT_STUDY_RECORD.ToxicityReproduction – v.8.5 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.DataSource
Materials and methods	Material and methods – common block Applicable test guideline, e.g: Reproductive toxicity (one-/two generation studies): <ul style="list-style-type: none"> - Method B.35 Two-generation reproduction toxicity study (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 416: Two- Generation Reproduction Toxicity. - OECD Test Guideline 443: 	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods

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	<p>Extended One-generation Reproduction Toxicity.</p> <ul style="list-style-type: none"> - pre-natal developmental toxicity studies - Method B.31 Prenatal developmental toxicity study (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 414: Prenatal developmental toxicity study. - OECD Test Guideline 426: Developmental neurotoxicity study. 		
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.LimitTest
Justification for study design	<p>A justification of the study design should be provided if the relevant test guideline used allows some flexibility, particularly regarding</p> <ul style="list-style-type: none"> - the selection of doses, - length of pre-mating exposure period, producing an F2 generation, - termination day for F2 generation, - including additional cohorts to assess developmental neurotoxicity and/or developmental immunotoxicity. 	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.JustificationForStudyDesign

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Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposureIfApplicable
Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter

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Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Vehicle	Select the vehicle used. If not available from picklist, select 'other'. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Details on mating procedure	Briefly describe the mating procedure. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnMatingProcedure

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	the respective regulatory programme.		
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

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	<p>dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.</p> <ul style="list-style-type: none"> - For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable. 		
<p>Duration of treatment / exposure</p>	<p>Indicate duration of treatment or exposure (with unit) for each reproductive phase and generation, e.g. (P) Males: [...] days/weeks before mating. (P) Females: [...]</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure</p>

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	<p>days/weeks before mating, [...]</p> <p>days/weeks during mating, [...]</p> <p>days/weeks during resulting pregnancies, [...]</p> <p>days/weeks through weaning of their F1 offspring. (F1) Males: [...]</p> <p>days/weeks at weaning, during growth into adulthood, mating and production of an F2 generation, until weaning of the F2 generation. (F1) Females: [...]</p> <p>days/weeks at weaning, during growth into adulthood, mating and production of an F2 generation, until weaning of the F2 generation.</p>		
Frequency of treatment	<p>Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	<p>Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet</p>		ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DosesConcentrations

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	,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Indicate number of animals used per dose group, e.g. [#] (P) males caged with [#] (P) females; [#] (F1) males, [#] (F1) females. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

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	Remarks text (e.g. '... see Table 1').		
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations

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<p>Parental animals: Observations and examinations</p>	<p>Indicate which clinical examinations were performed in the parental animals and the time schedule for those examinations. State if any examination was not performed and with what parental generation as applicable. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate tables(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If the study is a combined repeated dose toxicity / reproduction toxicity study or includes a developmental neurotoxicity part, include a note in the block 'Cross-reference' and describe these study parts separately in the respective data point entry form(s), i.e. 'Repeated dose toxicity (route x)' or 'Neurotoxicity'. Use freetext template</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.MaterialsAndMetho ds.Examinations.Parent alAnimalsObservationsA ndExaminations</p>
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	and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Oestrous cyclicity (parental animals)	Indicate whether and how [e.g., vaginal smear] and for how long [x cycles or x weeks] the oestrous cyclicity was determined. Indicate whether a screening for normal cycles (in a pre-treatment period) has been performed.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.OestrousCyclicityParentalAnimals
Sperm parameters (parental animals)	Indicate which sperm parameters were examined. State if any examination was not performed and with what parental generation as applicable. Also indicate the dose groups that were examined if not all.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.SpermParametersParentalAnimals
Litter observations	Indicate which litter observations were made. State if any examination was not performed and with what generation as applicable. Also indicate the dose groups that were examined if not all. In parentheses, include the time of observation (lactation day), e.g. (Day 0). As an	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.LitterObservations

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	<p>alternative option, include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
<p>Postmortem examinations (parental animals)</p>	<p>Indicate when the surviving parental males/females were sacrificed and the postmortem examinations performed. Use freetext template and delete/add elements as appropriate. As an alternative option, include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.PostmortemExaminationsParentalAnimals</p>

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	<p>sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
Postmortem examinations (offspring)	<p>Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined if not all. Use freetext template and delete/add elements as appropriate. As an alternative option or in addition, include a table and refer to respective table no. (use predefined or other appropriate table(s) if any and tailor it/them to your needs).</p> <p>Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.PostmortemExaminationsOffspring
Statistics	<p>List parameters that were analysed by which test methods. Indicate whether these are appropriate.</p> <p>Statistical analysis of e.g. anogenital distance (AGD) and nipple retention should be based on individual pup</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.Statistics

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	<p>data, taking litter effects into account. Where appropriate, the litter is the unit of analysis. Statistical analysis of pup body weight should be based on individual pup data, taking litter size into account. Due to the limited dimensions of some study (e.g. screening tests), statistical analyses in the form of tests for "significance" may be of limited value for many endpoints, especially reproductive endpoints. In these cases, some of the most widely used methods, especially parametric tests for measures of central tendency, are inappropriate. If statistical analyses are used then the method chosen should be appropriate for the distribution of the variable examined and be selected prior to the start of the study.</p> <p>Note: General statistical assumptions need not be stated unless there are deviations from generally applied techniques. Animals excluded from analyses should be in table footnotes.</p>		
Reproductive indices	Describe which reproductive indices	Multi-line text	ENDPOINT_STUDY_RE CORD.ToxicityReproduc

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	were calculated from breeding and parturition records of animals in the study. Include formulas or descriptions as provided in the study report.		tion.MaterialsAndMethods.Examinations.ReproductiveIndices
Offspring viability indices	Describe which viability indices were calculated from lactation records of litters in the study. Include formulas or descriptions as provided in the study report.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.OffspringViabilityIndices
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion
Results: P0 (first parental generation)		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration
General toxicity (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservClinSigns

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<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservClinSigns</p>
<p>Dermal irritation (if dermal study)</p>	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservDermalIrritationIfDermalStudy</p>
<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminatio</p>

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	<p>qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		nsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservDermalIrritationIfDermalStudy
Mortality	<p>Indicate whether mortality was observed and whether it was treatment-related or not.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservMortality
Description (incidence)	<p>Describe the incidence of mortality by sex and dose group. An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceMortality

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<p>Body weight and weight changes</p>	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. The effects should be also considered in relation to organ weight.</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservBodyweight</p>
<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservBodyweight</p>

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Food consumption and compound intake (if feeding study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservFoodConsum</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservFoodConsum</p>
Food efficiency	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.G</p>

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	examined' or 'not specified' as applicable.		eneralToxicityP0.ObservFoodEfficiency
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservFoodEfficiency
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservWaterConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussi

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	<p>At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		<p>on.ResultsOfExaminatio nsParentalGeneration.G eneralToxicityP0.Descri ptionIncidenceAndSeve rityObservWaterConsu m</p>
Ophthalmological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.G eneralToxicityP0.Observ Ophthalm</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the</p>	Text area	<p>ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.G eneralToxicityP0.Descri ptionIncidenceAndSeve rityObservOphthalm</p>

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	<p>effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Haematological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservHaematol
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservHaematol

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	<p>irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Clinical biochemistry findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservClinChem
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Effects seen on hormone levels should be described. Particularly with</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservClinChem

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	<p>comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Endocrine findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.EndocrineFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityEndocrine

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	<p>results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Urinalysis findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservUrIn
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservUrIn

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	the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservNeurobehaviour
Description (incidence and severity)	Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards). Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservNeurobehaviour

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	<p>results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Immunological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ImmunologicalFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityImmunologicalFindings

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	programme some form of a table(s) (predefined table) may be mandatory.		
Organ weight findings including organ / body weight ratios	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservOrganWeights
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Include (both) body weight, organ weights and relative weights (related to bw). Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservOrganWeights

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	of a table(s) (predefined table) may be mandatory.		
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservGrpathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservGrpathol
Neuropathological findings	Indicate whether any effects were observed	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduc

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	and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.		tion.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservNeuropathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservNeuropathol
Histopathological findings: non-neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservHistopathol

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<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description (using scores) where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservHistopathol</p>
<p>Histopathological findings: neoplastic</p>	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservHistopatholNeoplastic</p>
<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminatio</p>

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	<p>qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		nsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservHistopatholNeoplastic
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityOtherEffects

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	<p>adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Reproductive function / performance (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0
Reproductive function: oestrous cycle	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Indicate if it is oestrous cycles pre-treatment effects or treatment related.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.ObservEstrousParent
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussi

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	<p>minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		<p>on.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.DescriptionIncidenceAndSeverityOfbservEstrousParent</p>
Reproductive function: sperm measures	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.ObservSpecrmParent</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.Description</p>

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	<p>were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		IncidenceAndSeverityObservedParent
Reproductive performance	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.ObservedReproductiveParent
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.DescriptionIncidenceAndSeverityObservedReproductiveParent

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	<p>whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Details on results (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.DetailsOnResultsP0
	<p>Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.DetailsOnResultsP0.DetailsOnResults
Effect levels (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminatio

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			nsParentalGeneration.EffectLevelsP0.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.KeyResult
Dose descriptor	Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:') and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.Endpoint

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	absence of adverse toxic effects'.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.E ffectLevelsP0.Efflevel.Ef fectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.E ffectLevelsP0.Efflevel.B asedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.E

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			EffectLevelsP0.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.RemarksOnResults
Target system / organ toxicity (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0
	Record the target system(s) where		ENDPOINT_STUDY_RECORD.ToxicityReproduc

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	<p>toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.</p>		<p>tion.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	Check box	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.KeyResult</p>
Critical effects observed	<p>Flag to indicate if critical effects were observed in the study within specific organs or systems.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.CriticalEffectsObserved</p>
Lowest effective dose / conc.	<p>Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.</p>	Unit measure with Open List (Decimal)	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.LowestEffectiveDoseConc</p>
System	<p>Select any specific system where toxicity was observed that is considered of biological relevance.</p>	Open list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxic</p>

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			ityP0.TargetSystemOrg anToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.T argetSystemOrganToxic ityP0.TargetSystemOrg anToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.T argetSystemOrganToxic ityP0.TargetSystemOrg anToxicity.TreatmentRe lated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.T argetSystemOrganToxic ityP0.TargetSystemOrg anToxicity.DoseRespon seRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.T argetSystemOrganToxic ityP0.TargetSystemOrg anToxicity.RelevantFor Humans
Results: P1 (second parental generation)		Header 2	ENDPOINT_STUDY_RE CORD.ToxicityReproduc

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			tion.ResultsAndDiscussion.ResultsP1SecondParentalGeneration
General toxicity (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservClinSigns
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservClinSigns

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	programme some form of a table(s) (predefined table) may be mandatory.		
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservDermalIrritationIfDermalStudy
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservDermalIrritationIfDermalStudy

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Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservMortality
Description (incidence)	Describe the incidence of mortality by sex and dose group. An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceMortality
Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservBodyweight
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservBodyweight

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	<p>mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Food consumption and compound intake (if feeding study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservFoodConsum
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservFoodConsum

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	<p>the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Food efficiency	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservFoodEfficiency</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservFoodEfficiency</p>

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	(predefined table) may be mandatory.		
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservWaterConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservWaterConsum
Ophthalmological findings	Indicate whether any effects were observed and whether they were	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussi

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	treatment-related or not. Select 'not examined' or 'not specified' as applicable.		on.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservOphthalm
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservOphthalm
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservHaematol

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<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservHaematol</p>
<p>Clinical biochemistry findings</p>	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservClinChem</p>
<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.General</p>

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	<p>where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		IToxicityP1.DescriptionIncidenceAndSeverityObservClinChem
Endocrine findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.EndocrineFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen. Particularly with</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityEndocrine

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	<p>comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Urinalysis findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservUrIn
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservUrIn

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	incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservNeurobehaviour
Description (incidence and severity)	Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards). Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservNeurobehaviour

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	<p>comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Immunological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ImmunologicalFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityImmunologicalFindings

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	<p>accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Organ weight findings including organ / body weight ratios	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservOrganWeights
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservOrganWeights

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	<p>results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Gross pathological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservGrpat hol
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservGrpat hol

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	programme some form of a table(s) (predefined table) may be mandatory.		
Neuropathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservNeuropathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservNeuropathol

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Histopathological findings: non-neoplastic	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservHistopathol</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservHistopathol</p>
Histopathological findings: neoplastic	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.General</p>

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	examined' or 'not specified' as applicable.		IToxicityP1.ObservHisto patholNeoplastic
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservHistopatholNeoplastic
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

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	<p>At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		<p>on.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityOtherEffects</p>
Details on results	<p>Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DetailsOnResults</p>
Reproductive function / performance (P1)		Header 3	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1</p>

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<p>Reproductive function: oestrous cycle</p>	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.ReproductiveFunctionEstrousCycle</p>
<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.DescriptionIncidenceAndSeverityReproductiveFunctionEstrousCycle</p>
<p>Reproductive function: sperm measures</p>	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.Reprod</p>

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	examined' or 'not specified' as applicable.		activeFunctionPerformanceP1.ReproductiveFunctionSpermMeasures
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.DescriptionIncidenceAndSeverityReproductiveFunctionSpermMeasures
Reproductive performance	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.ReproductivePerformance

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<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.DescriptionIncidenceAndSeverityReproductivePerformance</p>
<p>Details on results (P1)</p>		<p>Header 3</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.DetailsOnResultsP1</p>
	<p>Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.DetailsOnResultsP1.DetailsOnResults</p>

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Effect levels (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.KeyResult
Dose descriptor	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.BasedOn

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	<p>fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification.</p> <p>Select 'not specified' if the effect concentration type is not known.</p>		
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.Basis
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.RemarksonResults

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	<ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' 		
Target system / organ toxicity (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1
	<p>Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s).</p> <p>Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.</p>		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduc

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	observed in the study within specific organs or systems.		tion.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related. Please indicate if maternal toxicity is seen.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondPar

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	dose-response manner (monotonic or non-monotonic).		entalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.RelevantForHumans
Results: F1 generation		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring
General toxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservClinOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservClinOffspring

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	<p>adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Dermal irritation (if dermal study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DermalIrritationOffspringIfDermalStudy
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityDermalIrritationOffspringIfDermalStudy

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	<p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Mortality / viability	<p>Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservViabilityOfspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservViabilityOffspring

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	<p>rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Body weight and weight changes	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Please indicate if maternal toxicity is seen.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservBodyweightOffspring</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservBodyweightOffspring</p>

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	incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservFoodConsumOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservFoodConsumOffspring

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	<p>significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Food efficiency	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservFoodEfficiencyOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservFoodEfficiencyOffspring

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	the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservWaterConsumOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservWaterConsumOffspring

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Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservOphthalmOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservOphthalmOffspring
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxi

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	examined' or 'not specified' as applicable.		cityF1.ObservHaematol Offspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservHaematolOffspring
Clinical biochemistry findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservClinChem Offspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussi

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	<p>At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		<p>on.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservClinChemOffspring</p>
Urinalysis findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservUrinOffspring</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservUrinOffspring</p>

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	<p>effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Sexual maturation	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservMaturatio nOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObserv Maturatio nOffspring

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	<p>irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Anogenital distance (AGD)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.AnogenitalDistance
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityAnogenitalDistance

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	<p>rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Nipple retention in male pups	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.NippleRetentionInMalePups
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityNippleRetentionInMalePups

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	<p>tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Organ weight findings including organ / body weight ratios	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Please indicate if maternal toxicity is seen.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservOrganWeightsOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservOrganWeightsOffspring

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	<p>toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Gross pathological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservGrpathOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Please indicate the scores of these malformations or number of pups where this is seen. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservGrpatholOffspring

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	<p>toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Histopathological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservHistopatholOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservHistopatholOffspring

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	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.OtherEffectsOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s)	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityOtherEffectsOffspring

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	(predefined table) may be mandatory.		
Developmental neurotoxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalNeurotoxicityF1
Behaviour (functional findings)	<p>Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards).</p> <p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalNeurotoxicityF1.BehaviourFunctionalFindings

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	the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalNeurotoxicityF1.DescriptionIncidenceAndSeverityBehaviourFunctionalFindings
Developmental immunotoxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalImmunotoxicityF1
Developmental immunotoxicity	Indicate whether any effects were observed	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduc

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	and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.		tion.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalImmunotoxicityF1.D developmentalImmunotoxicity
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalImmunotoxicityF1.D escriptionIncidenceAndSeverityDevelopmentalImmunotoxicity
Details on results (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DetailsOnResultsF1

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	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DetailsOnResultsF1.DetailsOnResults
Effect levels (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.KeyResult
Dose descriptor	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.Endpoint
Generation	Select the generation (e.g. 'P') the effect level refers to.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.Generation
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.EffectLevel

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	'<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.BasedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.Basis

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	select 'other:'. Any explanations can always be entered in the related supplementary text field.		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.RemarksOnResults
Target system / organ toxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1
	<p>Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s).</p> <p>Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship,</p>		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity

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	dose response relationship and relevance for humans.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.Organ

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Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.RelevantForHumans
Results: F2 generation		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation
General toxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservClinOffspring

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	examined' or 'not specified' as applicable.		
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservClinOffspring
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DermalIrritationOffspringIfDermalStudy
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

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	<p>At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		<p>on.ResultsF2Generation .GeneralToxicityF2.Desc riptionIncidenceAndSev erityDermalIrritationOff springIfDermalStudy</p>
Mortality / viability	<p>Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsF2Generation .GeneralToxicityF2.Obs ervViabilityOffspring</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect</p>	Text area	<p>ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsF2Generation .GeneralToxicityF2.Desc riptionIncidenceAndSev</p>

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	<p>related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		erityObservViabilityOffspring
Body weight and weight changes	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservBodyweightOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservBodyweightOffspring

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	<p>whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Food consumption and compound intake (if feeding study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservFoodConsumOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data,</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservFoodConsumOffspring

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	<p>include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Food efficiency	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservFoodEfficiencyOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservFoodEfficiencyOffspring

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	<p>tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Water consumption and compound intake (if drinking water study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservWaterConsumOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservWaterConsumOffspring

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	<p>the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Ophthalmological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservOphthalmOffspring</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservOphthalmOfspring</p>

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	of a table(s) (predefined table) may be mandatory.		
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservHaematolOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservHaematolOffspring
Clinical biochemistry findings	Indicate whether any effects were observed	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduc

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	and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.		tion.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservClinChemOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservClinChemOffspring
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservUrinOffspring

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<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservUrinOffspring</p>
<p>Sexual maturation</p>	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservMaturationOffspring</p>
<p>Description (incidence and severity)</p>	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.Desc</p>

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	<p>where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		<p>riptionIncidenceAndSeverityObservMaturatioOfspring</p>
Anogenital distance (AGD)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.AnogenitalDistance</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityAnogenitalDistance</p>

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	<p>and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Nipple retention in male pups	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.NippleRetentionInMalePups
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityNippleRetentionInMalePups

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	<p>irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Organ weight findings including organ / body weight ratios	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservOrganWeightsOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservOrganWeightsOffspring

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	<p>information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Gross pathological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservGrpatholOffspring</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservGrpatholOffspring</p>

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	<p>toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Histopathological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservHistopatholOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservHistopatholOffspring

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	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.OtherEffectsOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s)	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityOtherEffectsOffspring

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	(predefined table) may be mandatory.		
Developmental neurotoxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalNeurotoxicityOff1Generation
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalNeurotoxicityOff1Generation.BehaviourFunctionalFindings
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalNeurotoxicityOff1Generation.DescriptionIncidenceAndSeverityBehaviourFunctionalFindings

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	some form of a table(s) (predefined table) may be mandatory.		
Developmental immunotoxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalImmunotoxicityOff1Generation
Developmental immunotoxicity	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalImmunotoxicityOff1Generation.DevelopmentalImmunotoxicity
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalImmunotoxicityOff1Generation.DescriptionIncidenceAndSeverityDevelopmentalImmunotoxicity

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	regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Details on results (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DetailsOnResultsF2
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DetailsOnResultsF2.DetailsOnResults
Effect levels (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.KeyResult
Dose descriptor	Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:') and specify in the related text field). If the critical effects at	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.Endpoint

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	<p>a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>		
Generation	Select the generation (e.g. 'P') the effect level refers to.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.Generation
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation

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	ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.		.EffectLevelsF2.Efflevel. BasedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel. Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel. Basis
Remarks on result	This field can be used for: - giving a qualitative	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

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	<p>description of results in addition to or if no numeric value(s) were derived;</p> <ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' 		<p>on.ResultsF2Generation.EffectLevelsF2.Efflevel.RemarksOnResults</p>
Target system / organ toxicity (F2)		Header 3	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2</p>
	<p>Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.</p>		<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment</p>	Check box	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganTo</p>

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	or classification purpose.		xicityF2.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduc

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	reported in systems and/or organs are in a dose-response manner.		tion.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.RelevantForHumans
Overall reproductive toxicity		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity
	Record if reproductive toxicity was observed in the study. If yes, indicate the lowest effective dose / concentration, whether the reproductive effects occurred in the absence or presence of other toxic effects, are treatment and dose-response related and of human relevance.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.KeyResult
Reproductive effects observed	Flag to indicate if reproductive toxicity	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduc

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	was observed in the study.		tion.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.ReproductiveEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.LowestEffectiveDoseConc
Treatment related	Flag to indicate if the reproductive effects are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.TreatmentRelated
Relation to other toxic effects	Flag to indicate if the reproductive effects occur in the absence of other toxic effects or are or are not a secondary non-specific consequence of other toxic effects.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.RelationToOtherToxicEffects
Dose response relationship	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.RelevantForHumans
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

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			on.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ApplicantSummaryAndConclusion

5.6.1 Generational studies (includes reproduction toxicity to mammals) – Endpoint study record

<p>Purpose: Multigeneration studies (e.g. two-generation toxicity study and/or 1-extended one generation study) should be reported using the endpoint study record under 5.6-toxicity to reproduction. Other reproductive toxicity studies not covered by the endpoint study record under 5.6-toxicity to reproduction should be reported by using this template.</p>
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ENDPOINT_STUDY_RECORD.ToxicityReproductionOther - v.7.4 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.DataSource
Materials and methods	Material and methods – common block Type of method: Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field 'Any other information on materials and methods incl. tables'. If a specific template for in vitro assays is provided include the data in that template instead.	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.TestAnimals

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Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposureIfApplicable
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Close list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included:	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

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	<p>- For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable.</p> <p>If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.</p> <p>- For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable.</p> <p>- For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable.</p>		
Duration of treatment / exposure	Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Duration of test	Indicate the complete duration of the test.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DurationOfTest
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet, mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations

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Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Depending on type of study specify either number of dams or number of males and females.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Give details on the study design. As an option you may include an excerpt from the study report.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	List parameters that were analyzed by which test methods.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on material	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AnyOtherInform

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s and methods incl. tables			ationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion
Effect levels	<p>Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion.EffectLevels
Observed effects		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion.ObservedEffects
Any other information on results incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p>	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	<p>Overall remarks, attachments – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.OverallRemarksAttachments
Applicant's summary and conclusion	<p>Applicants summary and conclusion – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ApplicantSummaryAndConclusion

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5.6.2 Developmental toxicity studies (includes reproduction toxicity to mammals) – Endpoint study record

Purpose:

The developmental toxicity studies reported, taken together with other relevant data and information on the active substance, shall be sufficient to permit the assessment of effects on embryonic and foetal development, following repeated exposure to the active substance, and in particular shall be sufficient: (a) to identify direct and indirect effects on embryonic and foetal development resulting from exposure to the active substance; (b) to identify any maternal toxicity; (c) to establish the relationship between observed responses and dose in both dam and offspring; (d) to establish reference point (e.g. NOAELs) for maternal toxicity and pup development; (e) to provide additional information on adverse effects in pregnant as compared with non-pregnant females; (f) to provide additional information on any enhancement of general toxic effects of pregnant animals.

ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity - v.8.5 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Select species as appropriate. If not available from picklist, select 'other' and specify "i.e. rat or rabbit".	Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.TestAnimals
Administration /		Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTerato

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exposure			genicity.MaterialsAndMethods .AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Rout eOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Type OfInhalationExposureIfAppli cable
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Vehi cle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Mas sMedianAerodynamicDiamete r
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Geo metricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Rem arksOnMMAD
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Deta ilsOnExposure

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	requested by the respective regulatory programme.		
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Close list with remarks	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	<p>For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.</p> <p>Further route-dependent information to be included:</p> <ul style="list-style-type: none"> - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable. 	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Details on mating	Briefly describe the mating procedure. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods

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procedure	are requested by the respective regulatory programme.		.AdministrationExposure.DetailsOnMatingProcedure
Duration of treatment / exposure	Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	In the case of an inhalation or dermal study include the daily exposure duration, e.g. '4 hours per day'. Use of non-standard dosing regime should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.FrequencyOfTreatment
Duration of test	Indicate the complete duration of the test.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DurationOfTest
Doses / concentrations	Enter any remarks related to dose / concentration values.		ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DosesConcentrations
Dose / conc.	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter numeric value.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter number of females per dose, e.g. '20' or specify according to dose if different numbers were used and explain why. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.NoOfAnimalsPerSexPerDose

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	field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. Use data from range-finding study if available. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations
Maternal examinations	Indicate if and which examinations were performed in the dams and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. When tabulating parameters examined, refer to respective table no. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.MaternalExaminations
Ovaries and uterine content	Indicate if ovaries and uterine contents were examined and the type of examinations. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.OvariesAndUterineContent

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Blood sampling	Indicate if plasma or serum were examined and the type of examinations. Use freetext template to indicate the volume of whole blood examined.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.BloodSampling
Fetal examinations	Indicate if and which examinations were performed in the fetuses. Describe in detail, i.e. external, soft tissue and skeletal examinations, including assignment of fetuses and standard/non-standard methodologies used. Indicate how many per litter were used, i.e. all, half, a distinct number, or any other. When tabulating parameters examined, refer to respective table no. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.FetalExaminations
Statistics	List parameters that were analyzed by which test methods. Indicate whether these are appropriate. Differentiate between parametric and non-parametric analysis. Note: General statistical assumptions need not be stated unless there are deviations from generally applied techniques. Animals excluded from analyses should be in table footnotes.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.Statistics
Indices	Describe which indices were calculated from cesarean section records of animals in the study. Include formulas or descriptions as provided in the study report.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.Indices
Historical control data	Describe whether historical control data were provided to allow comparison with concurrent controls. State source of data and what data were included.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.HistoricalControlData
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and		Header 1	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato

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discussion			genicity.ResultsAndDiscussion
Results: maternal animals		Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals
General toxicity (maternal animals)	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 3	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.GeneralToxicityMaternalAnimals
Maternal developmental toxicity		Header 3	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity
Number of abortions	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.NumberOfAbortions
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityNumberOfAbortions
Pre- and post-implantation loss	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.PreAndPostImplantationLoss
Description	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTerato

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(incidence and severity)	description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		genicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityPreAndPostImplantationLoss
Total litter losses by resorption	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.TotalLitterLossesByResorption
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityTotalLitterLossesByResorption
Early or late resorptions	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.EarlyOrLateResorptions
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.

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severity)	whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		DescriptionIncidenceAndSeverityEarlyOrLateResorptions
Dead fetuses	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. DeadFetuses
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. DescriptionIncidenceAndSeverityDeadFetuses
Changes in pregnancy duration	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. ChangesInPregnancyDuration
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. DescriptionIncidenceAndSeverityChangesInPregnancyDuration

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	such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Changes in number of pregnant	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.ChangesInNumberOfPregnant
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityChangesInNumberOfPregnant
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityOtherEffects

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	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Details on maternal toxic effects	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.ResultsDetailsMaternal
Effect levels (maternal animals)	<p>Effect levels (OHT 67-69, 72-74) – common block</p> <p>Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.</p> <p>Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>	Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.EffectLevelsMaternalAnimals
Maternal abnormalities		Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities
	Record if any abnormalities were observed in the study and where they are located. Describe the incidence and severity of effects by dose group. Copy this block of fields for referring to different developmental endpoints where the indicated effect is located if the type of effects is different.		ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.MaternalAbnormalities
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.MaternalAbnormalities.KeyResult

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Abnormalities	Indicate whether any abnormalities were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Developmental abnormalities in dams include number of pregnant / non-pregnant dams, number of dams with abortions, early deliveries, stillbirths, resorptions and/or dead fetuses, mean number of implantations, live fetuses (pups), resorptions (early and late), dead fetuses, abortions and stillbirths per litter (with implants), pre and post implantation loss: number and percent, number of corpora lutea, duration of pregnancy, gravid uterine weight.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.Maternal Abnormalities.Abnormalities
Localisation	Select from the multiple drop-down list the developmental endpoint(s) where the indicated effect is located. Multiple items can be selected if they are all covered by the effects description given in the preceding field. Otherwise copy this block of fields and create additional lines as needed.	Multi select open list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.Maternal Abnormalities.Localisation
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.Maternal Abnormalities.Maternal Abnormalities.DescriptionIncidenceAndSeverity
Results (fetuses)		Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses
Fetal body weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalBodyWeightChanges

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Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverity
Reduction in number of live offspring	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ReductionInNumberOfLiveOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityReductionInNumberOfLiveOffspring
Changes in sex ratio	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ChangesInSexRatio
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionI

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severity)	whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		ncidenceAndSeverityChanges InSexRatio
Changes in litter size and weights	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.ResultsAndDiscussio n.ResultsFetuses.ChangesInLi tterSizeAndWeights
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.ResultsAndDiscussio n.ResultsFetuses.DescriptionI ncidenceAndSeverityChanges InLitterSizeAndWeights
Anogenital distance of all rodent fetuses	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.ResultsAndDiscussio n.ResultsFetuses.AnogenitalD istanceOfAllRodentFetuses
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.ResultsAndDiscussio n.ResultsFetuses.DescriptionI ncidenceAndSeverityChanges InAnogenitalDistance

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	<p>such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Changes in postnatal survival	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ChangesInPostnatalSurvival
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityChangesInPostnatalSurvival
External malformations	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ExternalMalformations
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityExternalMalformations

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	some form of a table(s) (predefined table) may be mandatory.		
Skeletal malformations	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.SkeletalMalformations
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeveritySkeletalMalformations
Visceral malformations	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.VisceralMalformations
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityVisceralMalformations
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion

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			n.ResultsFetuses.OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityOtherEffects
Details on embryotoxic / teratogenic effects	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ResultsDetailsDevelop
Effect levels (fetuses)	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.EffectLevelsFetuses
Fetal abnormalities		Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion

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			n.ResultsFetuses.FetalAbnormalities
	Record if any abnormalities were observed in the study and where they are located. Describe the incidence and severity of effects by dose group. Copy this block of fields for referring to different developmental endpoints where the indicated effect is located if the type of effects is different.		ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.KeyResult
Abnormalities	Indicate whether any abnormalities were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Fetal abnormalities include mean number and percent of live offspring; sex ratio; mean fetal/pup body weight by sex and with sexes combined; external, soft tissue and skeletal malformations and other relevant alterations; number and percent of fetuses and litters with malformations (including runts) and/or variations as well as description and incidences of malformations and main variations (and/or retardations).	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.Abnormalities
Localisation	Select from the multiple drop-down list the fetal endpoint(s) where the indicated effect is located. Multiple items can be selected if they are all covered by the effects description given in the preceding field. Otherwise copy this block of fields and create additional lines as needed.	Multi select open list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.Localisation
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.DescriptionIncidenceAndSeverity

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	some form of a table(s) (predefined table) may be mandatory.		
Overall developmental toxicity		Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity
	Record whether developmental toxicity was observed in the study. If yes, indicate the lowest effective dose / concentration, whether the developmental effects occurred in the absence or presence of maternal toxicity, are treatment and dose-response related and of human relevance.		ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.KeyResult
Developmental effects observed	Flag to indicate if developmental toxicity was observed in the study.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.DevelopmentalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.LowestEffectiveDoseConc
Treatment related	Flag to indicate if the reproductive effects are treatment related.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.TreatmentRelated
Relation to maternal toxicity	Flag to indicate if the reproductive effects occur in the absence of other toxic effects or are or are not a secondary non-specific consequence of other toxic effects.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.RelationToMaternalToxicity
Dose respons	Flag to indicate if the reproductive effects are in a dose-response manner.	Close d list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato

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e relationship			genicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the reproductive effects on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Close list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.RelevantForHumans
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks / attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ApplicantSummaryAndConclusion

5.7 Neurotoxicity studies, including delayed polyneuropathy studies – Endpoint Summary

Purpose:

The document should contain the information needed to be reported according to the list of end points for neurotoxicity (SANCO/12592/2012-rev. 2, 22 March 2019). Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

In case that there are not specific neurotoxicity studies available, a statement on whether neurotoxicity have been properly addressed in general toxicity studies and whether there is a neurotoxic potential should be included.

Please noted the developmental neurotoxicity studies should be reported under 5.6 by using the template reproductive toxicity.

ENDPOINT_SUMMARY.Neurotoxicity - v.6.2 (Final) [August 2020]

Name	Instructions	Type	Field Path
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Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.Neurotoxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment
Effect on neurotoxicity: via oral route		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaOralRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaOralRoute.LinkToRelevantStudyRecords
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL</p>	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaOralRoute.EndpointConclusion

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	<p>should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to neurotoxic effects. Other effects and dose descriptors should be reported in the section "Description of key information".</p> <p>Define the duration of the selected robust study summary in the relative field</p> <p>The species reported in the selected robust study summary should be reported in the relative field.</p>		
Effect on neurotoxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute.LinkToRelevantStudyRecords.Results
Endpoint conclusion	Endpoint conclusion (Species version) – common block	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurot

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	<p>“Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level. “No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level. If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to neurotoxic effects. Other effects and dose descriptors should be reported in the section “Description of key information”.</p> <p>Define the duration of the selected robust study summary in the relative field</p> <p>The species reported in the selected robust study summary should be reported in the relative field.</p>		<p>otoxicityViaInhalationRoute.EndpointConclusion</p>
<p>Effect on neurotoxicity: via dermal route</p>		<p>Header 2</p>	<p>ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAsse</p>

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			ssment.EffectOnNeurotoxicityViaDermalRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaDermalRoute.LinkToRelevantStudyRecords
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to neurotoxic effects. Other effects and dose descriptors should be reported in the section “Description of key information”.</p>	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaDermalRoute.EndpointConclusion

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	Define the duration of the selected robust study summary in the relative field		
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats . The template is also available in HTML format that can be easily uploaded in this textarea where relevant	Rich text area	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework.MoAAAnalysisHumanRelevanceFramework
Additional information	<p>Discussion(Header 1) – common block</p> <p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - Acute neurotoxicity (mention data if available, or 'study not required' if data are not required), and dose descriptor (e.g. NOAEL) - Repeated neurotoxicity (mention data if available, or 'study not required' if data are not required), 	Header 1	ENDPOINT_SUMMARY.Neurotoxicity.Discussion

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	<p>and dose descriptor (e.g. NOAEL)</p> <ul style="list-style-type: none"> - Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) (mention study results.), and dose descriptor (e.g. NOAEL) <p>If there is no additional information to be reported this field may be left empty.</p>		
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Neurotoxicity.JustificationForClassificationOrNonClassification
	<p>The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.</p>	Rich text area	ENDPOINT_SUMMARY.Neurotoxicity.JustificationForClassificationOrNonClassification.JustificationForClassification

5.7 Neurotoxicity studies, including delayed polyneuropathy studies– Endpoint study record

Purpose:

Such studies shall be performed for active substances with structures that are similar or related to those capable of inducing neurotoxicity, and for active substances which induce specific indications of potential neurotoxicity, neurological signs or neuropathological lesions in toxicity studies at dose levels not associated with marked general toxicity. Performance of such studies shall also be considered for substances with a neurotoxic mode of pesticidal action. Neurotoxicity studies in rodents shall provide sufficient data to evaluate the potential neurotoxicity of the active substance (neurobehavioural and neuropathological effects) after single and repeated exposure.

ENDPOINT_STUDY_RECORD.Neurotoxicity - v.9.5 (Final) [September 2020]

Name	Instructions	Type	Field Path
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Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.DataSource
Materials and methods	Material and methods – common block Applicable test guideline, e.g. "OECD 424 Method B.43".	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods
Test guideline			
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<'	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter

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	or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a	Text area	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

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	<p>justification should also be included briefly explaining the rationale of referring to another study.</p> <ul style="list-style-type: none"> - For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable. 		
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '28 days' or '18 months'.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet, mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			

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<p>No. of animals per sex per dose</p>	<p>Enter value or specify according to dose if different number of animals per dose or test, e.g. '10 in each dose group of FOB'.</p> <p>For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>For a developmental neurotoxicity study it should be noted: The method of animal assignment should have minimized potential problems related to litter effects, i.e., by using one pup/sex/litter (or one measure/litter, e.g., mean body weight for each litter).</p> <p>When allocating animals to FOB and motor activity testing, the same individual animals should have been evaluated at all scheduled time points.</p> <p>For the selection of animals and testing paradigms for cognitive (learning and memory) assessment, it is important to ensure that tasks were selected and/or animals allocated so that comparable assessments of learning were made at both times, i.e., shortly after PND 21 and around PND 60. Indicate whether the same or different animals were used for assessments at the weaning and adult ages. In general, the use of separate animals at the two time points is preferred, because for many tasks, initial learning (PND 21) may confound later (PND 60) assessment of learning. If the same animals were used at both times, different tasks would likely have been necessary. The selection of the test for assessing learning should have been adequately justified regardless of whether the same or a different task was used.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose</p>
<p>Control animals</p>	<p>Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.</p>	<p>Multi select open list with remarks</p>	<p>ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals</p>
<p>Details on study design</p>	<p>Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure</p>

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	<p>period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. For a developmental neurotoxicity study it should be noted: Dose selection rationale should be discussed, including information from the prenatal developmental or two-generation reproduction studies, if applicable. Any pilot study data (including biomarker data, such as cholinesterase activity) or pharmacokinetic data (e.g., milk or blood levels of test substance, or data that established time of peak effect) should be described in detail. If these data were submitted in a separate study report, the methods and results (including detailed tables of analytical results) should be presented in a separate record (include a reference in the block 'Cross-reference'); alternatively, they could be appended to this record.</p>		e.DetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations
Observations and clinical examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. When tabulating parameters examined, refer to respective table no.</p> <p>If other observations (e.g. haematology) are reported in another study summary (e.g. repeated dose toxicity), include a note in the block 'Cross-reference' and refer to that summary.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.ObservationsAndClinicalExaminationsPerformedAndFrequency
Specific biochemical examinations	<p>If specific biochemical determinations were made, provide details on the sampling, the tissues tested (e.g. plasma, whole blood, RBCs, brain (whole brain or regions)) and methodology. When tabulating parameters examined, refer to respective table no.</p> <p>Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not</p>	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.SpecificBiochemicalExaminations

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	applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Neurobehavioural examinations performed and frequency	<p>Provide details on the neurobehavioural examinations performed and frequency. Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables' and refer to respective table no., e.g. 'see Table 1' (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).</p>	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.NeurobehaviouralExaminationsPerformedAndFrequency
Sacrifice and (histo)pathology	<p>Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined.</p> <p>Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables' and refer to respective table no., e.g. 'see Table 1' (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).</p> <p>Specific guidance for acute or subchronic neurotoxicity: Indicate when and how were animals sacrificed, how many were perfused, what parameters were measured (e.g. brain weight, length and width), what were the procedures for perfusion, what tissues were evaluated, what type of staining was used, how were sections prepared (thickness, embedding media, number of sections). How many animals from each sex and treatment group were evaluated?</p> <p>Specific guidance for developmental neurotoxicity studies: see freetext template.</p> <p>Tables are optional, particularly for postmortem examinations of the offspring and the specific morphometric measures taken.</p>	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.SacrificeAndHistoPathology

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Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.OtherExaminations
Positive control	<p>Briefly describe the positive control data cited, and its acceptability for use with the current study. For positive control data to be acceptable, it must demonstrate the sensitivity of the test method to detect changes in the measured parameters. These data do not have to be from studies using prenatal exposures. However, the laboratory must demonstrate competence in evaluation of effects in neonatal animals perinatally exposed to chemicals and establish test norms for the appropriate age group. For observational measures, the data should demonstrate the ability to detect major neurotoxic endpoints, including limb weakness, paralysis, tremor, and autonomic signs; motor activity positive control data should demonstrate the ability to detect both increases and decreases in motor activity; pathology positive control data should demonstrate the ability to detect central and peripheral nervous system pathology (separate groups may be used to demonstrate each type of pathology, for example, acrylamide for peripheral nervous system pathology and trimethyl tin for central nervous system pathology).</p> <p>The methods should be completely described, and must be the same as those used in the study being evaluated (for example, the same equipment should be used, motor activity sessions should be of the same duration, the observation arena should be the same, the same sections should be evaluated for neuropathology, using the same types of stains, etc.), and preferably the same personnel should have conducted the testing. The data presentation should be complete enough to evaluate the sensitivity of the method, including individual data and measures of variability. Statistical evaluations used to demonstrate sensitivity should also be the same as those used in the study being evaluated. The number of animals per test group should not be greater than that used in the study under evaluation. Positive control data should also demonstrate inter-observer reliability for the FOB (i.e., the same results should be seen regardless of who is doing the observations). The positive control</p>	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.Positive Control

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	data should have been collected within a reasonable time frame before the current study, e.g., the last few years. New data should also be collected when observational personnel or other critical laboratory elements change.		
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsIncTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels
			ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.KeyResult
Dose descriptor	Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:') and specify in the related text field). If the critical effects at a specific	Open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.Endpoint

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	dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.BasedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is	Open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.

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	provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	ks (2000)	EffectLevels.Efflevel.RemarksOnResults
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.OverallRemarksAttachments
Applicants summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.ApplicantSummaryAndConclusion

5.8 Other toxicological studies- Endpoint Summary

Purpose:

Chemical (Active and Product): Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Other toxicological studies). This endpoint study record should be used for those studies where no specific IUCLID document is available. In certain cases, it can be necessary to carry out supplementary studies to further clarify the adverse human effects

Microorganisms (Active): Provide a summary of additional studies investigating chronic mammalian toxicity, pathogenicity and infectiveness, carcinogenicity and reproductive toxicity (if available). Provide only the most relevant details.

Microorganism (Product): Provide a summary of the additional information on mode of toxic action, toxicological profile and all other known toxicological aspects of the microorganism shall be submitted. Special attention shall be given to co-formulants. Provide a summary on additional acute toxicity studies for a combination of plant protection products where the product label includes requirements for the use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix.

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ENDPOINT_SUMMARY.AdditionalToxicologicalInformation - v.3.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	<p>Administrative data summary – common block Provide a brief description of additional toxicological studies and effects.</p>	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.AdministrativeDataSummary
Additional information	<p>Discussion (Header 1) – common block Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - An overview summary table with conclusion on the toxicological profile of metabolites (i.e. genotoxicity and general toxicity) found as residues in crops and/or livestock and/or in groundwater. - Supplementary studies on the active substance (State which study was performed and in what species and the outcome, if applicable also the NOAEL and LOAEL.) - Endocrine disrupting properties (State which study was performed and in what species and the outcome, if applicable also the NOAEL and LOAEL.) - Studies performed on metabolites or impurities. Especially the acute toxicity and genotoxicity should be highlighted. Present other parameters if more examined. <p>If there is no additional information to be reported this field may be left empty. <i>See IUCLID templates for PPP Risk Assessment - Template 5.4 - Template summary table on the assessment of the toxicological profile of metabolites</i> [http://doi.org/10.5281/zenodo.4557353]"</p>	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.Discussion

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5.8 Other toxicological studies - Endpoint study record

Purpose:

Under IUCLID if a metabolite is entered in the Metabolites Information document a dataset is created and the study should be reported in this dataset if the test material is the metabolite.

This endpoint study record should be used for those studies where not specific IUCLID document can be used.

As example, comparative in vitro metabolism studies should be currently reported by using this template.

In certain cases, it can be necessary to carry out supplementary studies to further clarify the adverse human effects.

In particular, if results from earlier studies indicate that the micro-organism may cause long-term health effects, studies on chronic toxicity, pathogenicity and infectiveness, carcinogenicity and reproductive toxicity must be carried out. Furthermore, where a toxin is produced, kinetic studies must be performed. Studies required must be designed on an individual basis, in the light of the particular parameters to be investigated and the objectives to be achieved. Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation - v.6.3 (Final) [September 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.Data Source
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods
Type of study / information	Indicate the type of information provided in this record and include any relevant information in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' and/or 'Overall remarks' as appropriate.	Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.TypeOfStudyInformation

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	Note: Include only information that does not fit into any of the specific chapters. Use chapter 'Specific investigations: other studies' for studies on behavioural effects, biochemical or cellular interactions, chemobiokinetics general studies, cytotoxicity, endocrine system modulation, hematotoxicity, hepatotoxicity, mechanistic studies, methaemoglobinaemia, nephrotoxicity, phototoxicity, respiratory irritation, splenic toxicity, or toxicogenomics.		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ApplicantSummaryAndConclusion

5.8.2.1 Immunotoxicity – Endpoint Summary

Purpose:

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be: species, outcome also reference points (e.g. NOAEL)., if applicable.

In case that there are not specific immunotoxicity studies available, a statement on whether immunotoxicity has been properly addressed in general toxicity studies and whether there is a immunotoxicity potential should be included.

Please note the developmental immunotoxicity studies should be reported under 5.6 by using the template reproductive toxicity.

(Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

ENDPOINT_SUMMARY.Immunotoxicity - v.6.2 (Final) [August 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of the immunotoxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.Immunotoxicity.AdministrativeDataSummary
		Rich text area	ENDPOINT_SUMMARY.Immunotoxicity.KeyInformation.KeyInformation
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment

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Effect on immunotoxicity: via oral route		Header 2	ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss essment.EffectOnImmu notoxicityViaOralRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss essment.EffectOnImmu notoxicityViaOralRoute. LinkToRelevantStudyRe cords
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to immunotoxic effects. Other effects and dose descriptors should be reported in the section</p>	Header 3	ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss essment.EffectOnImmu notoxicityViaOralRoute. EndpointConclusion

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	<p>“Description of key information”.</p> <p>Define the duration of the selected robust study summary.</p> <p>The species reported in the selected robust study summary should be reported in the relative field .</p>		
Effect on immunotoxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaInhalationRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaInhalationRoute.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaInhalationRoute.LinkToRelevantStudyRecords.Results
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit</p>	Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaInhalationRoute.EndpointConclusion

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	<p>dose level. If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to immunotoxic effects. Other effects and dose descriptors should be reported in the section “Description of key information”.</p> <p>Define the duration of the selected robust study summary.</p> <p>The species reported in the selected robust study summary should be reported in the relative field .</p>		
Effect on immunotoxicity: via dermal route		Header 2	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaDermalRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaDermalRoute.LinkToRelevantStudyRecords

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<p>Endpoint conclusion</p>	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to immunotoxic effects. Other effects and dose descriptors should be reported in the section “Description of key information”.</p> <p>Define the duration of the selected robust study summary.</p> <p>The species reported in the selected robust study summary should be reported in the relative field .</p>	<p>Header 3</p>	<p>ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss essment.EffectOnImmu notoxicityViaDermalRou te.EndpointConclusion</p>
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Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats . The template is also available in HTML format that can be easily uploaded in this textarea where relevant	Rich text area	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Immunotoxicity.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Immunotoxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Immunotoxicity.JustificationForClassificationOrNonClassification.JustificationForClassificationOrNonClassification

5.8.2.1 Immunotoxicity – Endpoint study record

Purpose:

Supplementary studies shall be carried out on the immunotoxicological potential where they are necessary to further clarify observed effects taking into account the results of the available toxicological and metabolism studies and the most important exposure routes.

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ENDPOINT_STUDY_RECORD.Immunotoxicity - v.7.5 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter

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Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Close list with remarks	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

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	<p>- For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable.</p> <p>- For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable.</p>		
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '28 days' or '18 months'.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet, mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Administration

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	<p>recovery group if applicable.</p> <p>For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>		Exposure.NoOfAnimalsPerSexPerDose
Control animals	<p>Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	<p>Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations
Observations and clinical examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If other observations (e.g. haematology) are reported in another study summary (e.g. repeated dose toxicity), include a note in the block 'Cross-</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.ObservationsAndClinicalExaminationsPerformedAndFrequency

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	reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.SacrificeAndPathology
Cell viabilities	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.CellViabilities
Humoral immunity examinations	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Example of brief description of protocol: 'Spleen IgM antibody response to a T-dependent antigen, sheep erythrocytes (sRBC) - Day 4 response: Animals were exposed to the test substance or positive control for 28 days, then injected intravenously to sheep erythrocytes on day 25. On day 29 (peak day of IgM response), the animals were sacrificed, spleens were removed and weighed, then spleen cells were prepared on day 30. The primary response to sheep erythrocytes	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.HumoralImmunityExaminations

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	<p>was measured using a modified hemolytic plaque assay (Jerne, N.K., et al., Plaque forming cells: Methodology and Theory. Transpl. Rev. 18:130-191, 1974). Cell counts were performed and the number of cells/spleen, AFC/spleen and AFC/106 spleen cells were determined.'</p> <p>Example of brief description of protocol for Enzyme-Linked Immunosorbent Assay (ELISA): 'The effects of test substance on antibody response to antigen were determined by an ELISA using methods described by Temple et al. (1995). Test animals were dosed with test material for ... days. Animals were exposed to sheep erythrocytes on day...IgM titers in serum were determined ... days after immunization.'</p>		
Specific cell-mediated immunity	<p>Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Describe cell harvest and culture and proliferation measurement ((3H) thymidine) incorporation, etc.</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.SpecificCellMediatedImmunity
Non-specific cell-mediated immunity	<p>Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Example of brief description of protocol: 'Following ... days of exposure to test material or positive control, the effects of test substance on spontaneous cytotoxic activity were determined by incubating splenocytes from treated and control animals with 51Cr-labeled YAC-1 lymphoma cells (target cell). Following a 4-hour incubation period, the amount of radiolabel released from target cells was determined (measure of NK cytotoxicity).'</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.NonSpecificCellMediatedImmunity
Other functional	<p>Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.

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<p>activity assays</p>	<p>appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Example of brief description of protocol: 'On day 30, a single cell suspension was prepared from each spleen and incubated in flat bottom microtiter plates (RPMI media supplemented with 10% fetal bovine serum and 5x10⁻⁵ 2-mercaptoethanol). The spleen cells were cultured in either non-treated or anti-CD3-treated wells (100 µL of 1 µg/mL anti-CD3) and incubated at 4°C overnight. Prior to harvest on day 3, the cells were pulsed with 3H-thymidine for 18-24 hours.'</p> <p>Example of brief description of protocol for enumeration total B cells, total T cells and T cell subpopulations: 'Following ... days of dosing, single cell preparations from each spleen were seeded at 1x10⁶ cells/well into a 96-well microtiter plate. Phenotypic analysis of total B cell, T cell, and T cell subpopulations were conducted using monoclonal antibody conjugates to fluorescein isothiocyanate (FITC) or phycoerythrin (PE). The specific monoclonal antibodies used were: OX19 conjugated to PE to enumerate total T-cells (CD5+), OX38 conjugated to FITC to enumerate CD4+ cells (T helper cells) and OX8 conjugated to FITC to enumerate CD8+ cells (T suppressor/cytotoxic cells). For both the CD4+ and CD8+ cells, a double label with OX19 was used. OX33 conjugated to FITC was used to enumerate CD45+ (B lymphocytes). Following the initial staining with antibody and washing with staining buffer, the DNA specific fluorescent stain propidium iodide (PI) was added to each well as a viability stain. Following a 5 minute incubation with PI, the cells were washed once with staining buffer and then enumerated on a Coulter Epics XL-MCL Flow Cytometer. At least 5,000 cells were counted for each sample.'</p>		<p>OtherFunctionalActivityAssays</p>
<p>Other examinations</p>	<p>Describe any other examinations.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Examinations. OtherExaminations</p>

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Positive control	Briefly describe the positive control data cited, and its acceptability for use with the current study. Criteria for acceptability include the positive demonstration of sensitivity of the test methods to detect changes in the measured parameters.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.PositiveControl
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations
Specific immunotoxic examinations		Header 3	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations
Cell viabilities	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Close list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.CellViabilities
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityCellViabilities

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	<p>table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Humoral immunity examinations	<p>Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.</p>	Close d list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.HumoralImmunityExaminations
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityHumoralImmunityExaminations
Specific cell-mediated immunity	<p>Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.</p>	Close d list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.SpecificCellMediatedImmunity
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such</p>	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeveritySpecificCellMediatedImmunity

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	<p>tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Non-specific cell-mediated immunity	<p>Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.</p>	Close d list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.NonSpecificCellMediatedImmunity
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityNonSpecificCellMediatedImmunity
Other functional activity assays	<p>Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.</p>	Close d list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.OtherFunctionalActivityAssays
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the</p>	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityOtherFunctionalActivityAssays

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	<p>details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Close d list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.OtherFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityOtherFindings
Effect levels	Effect levels (OHT 67-69, 72-74) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.ApplicantSummaryAndConclusion
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5.8.2.2 Toxic effects on livestock – Endpoint summary

Purpose:

Summary information of to the most relevant study(ies) providing data to establish maximum residue levels for food of animal origin. In case studies on toxic effects on livestock are available (currently not a data requirement under EU pesticide legislation) should be summarised by using this template. It is not mandatory to fill this template in case there are not data available.

ENDPOINT_SUMMARY.ToxicEffectsLivestockPets - v.5.0 (Final) [July 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of the relevant study and effects	Header 1	ENDPOINT_SUMMARY.ToxicEffectsLivestockPets.AdministrativeDataSummary
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicEffectsLivestockPets.Discussion

5.8.2.2 Toxic effects on livestock – Endpoint study record

Purpose:

Provide data in order to determine the residue in products of animal origin which will result from residues in feedingstuffs or fodder crops.

ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock - v.6.4 (Final) [September 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 503 study on metabolism.	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.MaterialsAndMethods.TestAnimals
Route of exposure	Indicate to which route of exposure the information or description of experimental study refers to.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.MaterialsAndMethods.AdministrationExposure.RouteOfExposure
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify. If no vehicle was used, select 'unchanged (no vehicle)'. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks	Text area	ENDPOINT_STUDY_RECORD.ToxicEffectsLivesTock.MaterialsAndMethods

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<p>n of doses or concentrations</p>	<p>field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.</p> <p>Further route-dependent information to be included:</p> <ul style="list-style-type: none"> - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. - If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable. 		<p>ods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations</p>
<p>Duration of treatment / exposure</p>	<p>Indicate duration in days, weeks or months, e.g. '5 days' or '10 weeks'.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure</p>
<p>Frequency of treatment</p>	<p>Indicate the frequency of the administration of doses to the test animals (e.g., 'once' or 'daily injections' or '2 doses per day, 7 days per week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment</p>
<p>Post exposure period</p>	<p>Indicate observation period (in days, weeks, months) after last exposure to the test material.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.PostExposurePeriod</p>

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Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify if different number of animals were used per sex and/or dose level.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Further details on study design	Include any details on the study design including a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level),	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.FurtherDetailsOnStudyDesign

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	<p>animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
Examinations		Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	<p>Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations.OtherExaminations

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Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion
Clinical signs and mortality	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Close d list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservClinSigns
Body weight and weight gain	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Close d list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservBodyweight
Food consumption and compound intake (if feeding study)	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Close d list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservFoodConsum
Water consumption and compound intake (if drinking)	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Close d list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservWaterConsum

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water study)	Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.		
Haematology	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Close d list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservHaematol
Clinical chemistry	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Close d list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservClinChem
Urinalysis	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Close d list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservUrin
Gross pathology and organ weights	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Close d list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservGrpathol
Histopathology	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Close d list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservHistopathol
Details on results	Describe the effects by dose level for each of the previous fields answered 'yes'. If answered 'no effects', you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ResultsDetails

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	<p>for evaluating this study summary or that are requested by the respective regulatory programme. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables' and refer to respective table no., e.g. 'see Table 1' (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.</p>		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.OverallRemarksAttachments
Applicants summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ApplicantSummaryAndConclusion

Links to support material:

Guidelines for residue data under Directive 91/414/EEC and Regulation EC 396/2005 (Appendix G-livestock feeding studies):

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-g.pdf

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5.8.3 Endocrine disrupting properties (includes ecotoxicity studies on terrestrial vertebrates) – Flexible summary

Purpose:

To report the assessment of the endocrine disrupting (ED) properties (for both human health and the environment) according to the ECHA/EFSA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.

Endpoint Study Records of individual mammalian toxicology ED studies should be included under 5.8.3 and 5.8.4 whereas Endpoint Study Records of individual ecotoxicology ED studies are presented under 8.2.3. Please add under this section cross references to the respective Endpoint Study Records are presented.

Besides presenting the conclusions of the weight of evidence assessment, it is also requested to make a proposal for a further testing strategy where this is necessary to conclude the ED assessment (e.g. in case the data package is insufficient) and timeline for the execution of the additional study/ies proposed in the strategy. The conclusions of the weight of evidence assessment should be complemented by the inclusion of the substantiating line of evidence and of the mode of action (MoA) analysis.

In the ECHA/EFSA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, particular instructions on how to present the assessment are provided. The applicant is kindly requested to present the assessment in line with the Guidance document. Furthermore, the Excel file, completed in line with the template for reporting the available information relevant for ED assessment (Appendix E.1 to the Guidance) should be submitted as attachment.

This document replaces Appendix I.

FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest – v.1.2 (Final) [October 2020]			
Name	Instructions	Type	Field Path
Administrative data		Header 1	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.EndocrineDisruptingProperties

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			AssessmentP est.Administr ativeDataSu mmary.DataP rotection
ED assessm ent		Header 1	FLEXIBLE_SU MMARY.Endo crineDisrupti ngProperties AssessmentP est.EdAssess ment
Assessm ent of ED for humans (T-modality)		Header 2	FLEXIBLE_SU MMARY.Endo crineDisrupti ngProperties AssessmentP est.EdAssess ment.EdForH umansTmoda lity
Assessm ent of the lines of evidence		Header 3	FLEXIBLE_SU MMARY.Endo crineDisrupti ngProperties AssessmentP est.EdAssess ment.EdForH umansTmoda lity.Assessme ntLinesOfEvid ence
Have T-mediate d paramet ers been sufficient ly investiga ted?	Provide an assessment for the following information by specifying if the <u>T-mediated adversity in humans</u> has been sufficiently investigated (or not) and the rationale	Closed list with remarks	FLEXIBLE_SU MMARY.Endo crineDisrupti ngProperties AssessmentP est.EdAssess ment.EdForH umansTmoda lity.Assessme ntLinesOfEvid ence.Sufficie ntInvestigati onT

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<p>Lines of evidence for adverse effects</p>	<p>List the relevant lines of evidence for adversity (also using a tabular representation).</p> <p>Example: WoE for T-mediated adversity</p> <ul style="list-style-type: none"> Thyroid histological changes (follicular dilatation, FC hyperplasia and FC adenoma) observed in two species (mouse and rat) in the carcinogenesis studies (study ID x and y) and considered adverse (intermediate and high doses). The two carcinogenesis studies were conducted at the MTD. Based on survival, body weight, food consumption, clinical chemistry and clinical signs The proliferative effect was confirmed by an increase in cell proliferation observed in a short study (up to 28 days) and lower dose (time & dose concordance). Additional target organ toxicity was observed in the adrenal, kidney (only mouse) and liver at the same doses (relevant for consideration on potential non-endocrine MOA) For the liver, changes were mainly characterized by panlobular hypertrophy, hepatocellular necrosis, fatty change and hepatocellular neoplasm. Considered adverse and observed in multiple studies also of shorter duration (likely lead toxic effect) 	<p>Rich text area</p>	<p>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansModality.AssessmentLinesOfEvidence.EvidenceAdverseEffects</p>
<p>Lines of evidence for endocrine activity</p>	<p>List the relevant lines of evidence for endocrine activity (also using a tabular representation).</p> <p>Example: WoE for T-mediated endocrine activity</p> <ul style="list-style-type: none"> TPO in vitro investigation negative Decrease in THs in the mouse was observed in studies of shorter duration (14 and 28 days) and at lower doses (35 and 350 mg/kg/day). 	<p>Rich text area</p>	<p>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansModality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity</p>

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	<ul style="list-style-type: none"> Decrease in THs in the rat was observed in a study of shorter duration (14 days) and dose tested of 700 mg/kg bw per day. Increase at week 16 only in TSH (measured in rat and mouse) were observed in mouse. 		
WoE for adversity and endocrine activity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to then select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity
Has endocrine activity been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>T-mediated endocrine activity in humans</u> has been sufficiently investigated (or not) and the rationale.	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated
Selection of relevant scenario	In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansTmodality

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	<p>For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.</p> <p>Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.</p> <p>Selection of relevant scenario</p> <table border="1" data-bbox="357 598 1076 1747"> <thead> <tr> <th data-bbox="357 598 535 793">Adversity based on T-mediated parameters</th> <th data-bbox="535 598 691 793">Positive mechanistic OECD CF level 2/3 Test</th> <th data-bbox="691 598 797 793">Scenario</th> <th data-bbox="797 598 1076 793">Next step of the assessment</th> </tr> </thead> <tbody> <tr> <td data-bbox="357 793 535 955">No (sufficiently investigated)</td> <td data-bbox="535 793 691 955">Yes/No</td> <td data-bbox="691 793 797 955">1a</td> <td data-bbox="797 793 1076 955">Conclude: ED criteria not met because there is not "T-mediated" adversity</td> </tr> <tr> <td data-bbox="357 955 535 1117">Yes (sufficiently investigated)</td> <td data-bbox="535 955 691 1117">Yes/No</td> <td data-bbox="691 955 797 1117">1b</td> <td data-bbox="797 955 1076 1117">Perform MoA analysis</td> </tr> <tr> <td data-bbox="357 1117 535 1312">No (not sufficiently investigated)</td> <td data-bbox="535 1117 691 1312">Yes</td> <td data-bbox="691 1117 797 1312">2a (i)</td> <td data-bbox="797 1117 1076 1312">Perform MoA analysis (additional information may be needed for the analysis)</td> </tr> <tr> <td data-bbox="357 1312 535 1507">No (not sufficiently investigated)</td> <td data-bbox="535 1312 691 1507">No (sufficiently investigated)</td> <td data-bbox="691 1312 797 1507">2a (ii)</td> <td data-bbox="797 1312 1076 1507">Conclude: ED criteria not met because no T-mediated endocrine activity observed</td> </tr> <tr> <td data-bbox="357 1507 535 1747">No (not sufficiently investigated)</td> <td data-bbox="535 1507 691 1747">No (not sufficiently investigated)</td> <td data-bbox="691 1507 797 1747">2a (iii)</td> <td data-bbox="797 1507 1076 1747">Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters.</td> </tr> </tbody> </table>	Adversity based on T-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment	No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not " T-mediated " adversity	Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis	No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)	No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no T-mediated endocrine activity observed	No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters.	<p>lity.AssessmentLinesOfEvidence.SelectionOfRelevantScenario</p>
Adversity based on T-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment																							
No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not " T-mediated " adversity																							
Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis																							
No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)																							
No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no T-mediated endocrine activity observed																							
No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters.																							

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				Depending on the outcome move to corresponding scenario		
	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis		
MoA analysis	<p>The fields in the MoA analysis fields should be completed only for scenarios 1b, 2a(i) and 2b.</p> <p>In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis."</p> <p>Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.</p>			Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansTmodality.MoaAnalysis	
Postulated MoA	<p>Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be in the field 'Conclusion on MoA Analysis'.</p>				FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansTmodality.MoaAnalysis.PostulatedMoa	
Name of postulated MoA	<p>Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.</p>			Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansTmodality	

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			lity.MoaAnalysis.PostulatedMoa.PostulatedMoa
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, ..., AO.	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansModality.MoaAnalysis.PostulatedMoa.EventType
Event description	Description of the event e.g. TSH; increased or Nuclear receptor activation (liver).	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansModality.MoaAnalysis.PostulatedMoa.EventDescription
Supporting evidence	Supporting evidence at the Lowest Observable Adverse Effect Level e.g. One-generation study (64.6 mg/kg/day in dam).	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansModality.MoaAnalysis.PostulatedMoa.SupportingEvidence
Link to relevant study records	Link to the reference entity for the supporting evidence.	Literature reference list	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssess

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			ment.EdForHumansTmodality.MoaAnalysis.PostulatedMoa.RelevantRecords																												
Postulated MoA																															
Empirical support	<p>When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document. Example Dose: and temporal-concordance between key events of the postulated MoA</p> <table border="1"> <thead> <tr> <th></th> <th>MIE CAR- PXR activation</th> <th>KE1 Phase I /Phase II catabolic activation</th> <th>KE2 ↓serum concentration of T4</th> <th>KE3 ↑ in TSH</th> <th>KE4 ↑ in follicular cells proliferation</th> <th>AO Thyroid hyperplasia/ adenoma</th> </tr> </thead> <tbody> <tr> <td><i>In vitro</i> 3-10 µM</td> <td>96 hours +++</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>35 mg/kg bw per day mouse</td> <td>7-28 days +++</td> <td>7-28 days +++</td> <td>7-28 days ++</td> <td>7-28 days ++</td> <td>7-28 days ++</td> <td></td> </tr> <tr> <td>460 (mouse)/ 318 (rat) mg/kg bw per day</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>104 weeks +</td> </tr> </tbody> </table>		MIE CAR- PXR activation	KE1 Phase I /Phase II catabolic activation	KE2 ↓serum concentration of T4	KE3 ↑ in TSH	KE4 ↑ in follicular cells proliferation	AO Thyroid hyperplasia/ adenoma	<i>In vitro</i> 3-10 µM	96 hours +++						35 mg/kg bw per day mouse	7-28 days +++	7-28 days +++	7-28 days ++	7-28 days ++	7-28 days ++		460 (mouse)/ 318 (rat) mg/kg bw per day						104 weeks +	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis.EmpiricalSupport
	MIE CAR- PXR activation	KE1 Phase I /Phase II catabolic activation	KE2 ↓serum concentration of T4	KE3 ↑ in TSH	KE4 ↑ in follicular cells proliferation	AO Thyroid hyperplasia/ adenoma																									
<i>In vitro</i> 3-10 µM	96 hours +++																														
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460 (mouse)/ 318 (rat) mg/kg bw per day						104 weeks +																									
Conclusion on MoA analysis	<p>The conclusion of the MoA analysis should be presented in a tabular form. In this section, when relevant, comparative MoA analysis can be reported as well.</p>	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentP																												

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<p>When more than one MoA is postulated, include a conclusion for each MoA postulated.</p> <p>Example: Summary of the MoA analysis</p>							<p>est.EdAssessment.EdForHumansTmodality.MoaAnalysis.ConclusionOnMoa</p>
	MIE to KE1	KE1 to KE2	KE2 to KE3	KE3 to KE4	KE4 to KE5	KE5 to AO	
Biological plausibility for the KER	Strong, well documented	Strong, well documented	Strong, well documented	Strong, well documented	Strong, well documented	Strong, well documented	
Empirical support for the KER	Moderate, /strong, some evidence is indirect	Moderate, evidence is indirect, THs clearance was not measured	Moderate, only in one species and occasionally controversial	Strong, dose and time related	Strong dose and time related	Strong, dose and time related	
Essentiality of the KE	Strong	Na	Na	Na	Na	Na	
Consistency	<p>Some KEs are consistently observed in different studies and species</p> <p>The pattern of effect is consistent across studies and species and in line with the postulated MOA</p>						
Analogy	<p>The same MOA has been seen in the same species with multiple substances and this is well documented</p>						

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	Specificity	This MOA is not very specific and can occur as a consequence of activation of different MIE. However, the upstream KEs are specific of a liver mediated MIE. As such, this MOA is specific.		
Uncertainty analysis			Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansTmodality.UncertaintyAnalysis
Uncertainty analysis		List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and uncertainty associated with methodology e.g. excluded factors		FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansTmodality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties		Describe each uncertainty related to the both MoA analysis and assessment of the lines of evidence.	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansTmodality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification		Characterise the overall impact of the source of uncertainty on the assessment conclusion	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingProperties

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			AssessmentP est.EdAssess ment.EdForH umansTmoda lity.Uncertain tyAnalysis.Un certaintyAnal ysis.Justificati on
Uncertai nty analysis			
Assessm ent of ED for humans (EAS- modality)		Header 2	FLEXIBLE_SU MMARY.Endo crineDisrupti ngProperties AssessmentP est.EdAssess ment.EdForH umansEasmo dality
Assessm ent of the lines of evidence		Header 3	FLEXIBLE_SU MMARY.Endo crineDisrupti ngProperties AssessmentP est.EdAssess ment.EdForH umansEasmo dality.Assess mentLinesOf Evidence
Have EAS- mediate d paramet ers been sufficient ly investiga ted?	Provide an assessment for the following information by specifying if the <u>EAS-mediated adversity in humans</u> has been sufficiently investigated (or not) and the rationale	Closed list with remarks	FLEXIBLE_SU MMARY.Endo crineDisrupti ngProperties AssessmentP est.EdAssess ment.EdForH umansEasmo dality.Assess mentLinesOf Evidence.Suff icientInvestig ationEas

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<p>Lines of evidence for adverse effects</p>	<p>List the relevant lines of evidence for adversity (also using a tabular representation).</p> <p>Example: WoE for EAS-mediated adversity</p> <ul style="list-style-type: none"> The most relevant studies for adversity are 2 two-years rat studies Leydig cells adenoma observed in 2 two-year rat studies. Dose-dependent increase observed below MTD. Dose-dependent decrease of testis weight observed in 1 two-year rat study. Effect observed below MTD. The two carcinogenesis studies were conducted at the MTD. (Based on survival, body weight, food consumption, clinical chemistry and clinical signs). Additional target organ toxicity was observed in the liver. 	<p>Rich text area</p>	<p>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.EvidenceAdverseEffects</p>
<p>Lines of evidence for endocrine activity</p>	<p>List the relevant lines of evidence for endocrine activity (also using a tabular representation).</p> <p>Example: WoE for EAS-mediated endocrine activity</p> <ul style="list-style-type: none"> Several <i>in vitro</i> assays providing evidence indicative of anti-androgenic activity. Decreased serum testosterone and increased testicular testosterone in 90-days rat study in male. Increased LH levels (rat 2-weeks) in males. 	<p>Rich text area</p>	<p>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity</p>

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	<ul style="list-style-type: none"> Decreased weight of several male reproductive organs from 3 Hershberger studies. 		
WoE for adversity and endocrine activity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to then select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity
Has endocrine activity been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>EAS-mediated endocrine activity in humans</u> has been sufficiently investigated (or not) and the rationale.	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated
Selection of relevant scenario	<p>In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.</p> <p>For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.</p> <p>Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.</p>	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.SelectionOfRelevantScenario

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Selection of relevant scenario			
Example: Selection of relevant scenario			
Adversity based on EAS-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment
No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not "EAS-mediated" adversity
Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis
No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)
No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no EAS-mediated endocrine activity observed
No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario

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	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis		
	<p>In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis."</p> <p>Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.</p>					
MoA analysis	<p>The following fields should be completed only for scenarios 1b, 2a(i) and 2b.</p> <p>In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis."</p> <p>Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.</p>				Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.MoAAnalysis
Postulated MoA	<p>Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be reflected here.</p>					FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.MoAAn

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			alysis.PostulatedMoa
Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.PostulatedMoa
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, ..., AO.	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.Event Type
Event description	Description of the event e.g. LH; increased or Leydig cells hyperplasia	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.Event Description
Supporting evidence	Supporting evidence at the Lowest Observable Adverse Effect Level e.g. One-generation study (64.6 mg/kg/day in dam).	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmo

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			dality.MoaAnalysis.PostulatedMoa.SupportingEvidence																												
Link to relevant study records	Link to the reference entity for the supporting evidence.	Literature reference list	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.RelevantRecords																												
Postulated MoA																															
Empirical support	<p>When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document.</p> <p>Example: Dose- and temporal-concordance between key events of the postulated MoA</p> <table border="1"> <thead> <tr> <th></th> <th>MIE</th> <th>KE1</th> <th>KE2</th> <th>KE3</th> <th>KE4</th> <th>AO</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td>↓ serum testosterone</td> <td>↑ LH levels</td> <td>↑ testicular testosterone</td> <td>Leydig cells hyperplasia</td> <td>Leydig cells tumors</td> </tr> <tr> <td>6.25 mg/kg bw per day (rat)</td> <td></td> <td></td> <td></td> <td></td> <td>104 weeks ++</td> <td>104 weeks ++</td> </tr> <tr> <td>10 mg/kg bw per day (rat)</td> <td></td> <td></td> <td></td> <td></td> <td>117 weeks ++</td> <td>117 weeks ++</td> </tr> </tbody> </table>		MIE	KE1	KE2	KE3	KE4	AO			↓ serum testosterone	↑ LH levels	↑ testicular testosterone	Leydig cells hyperplasia	Leydig cells tumors	6.25 mg/kg bw per day (rat)					104 weeks ++	104 weeks ++	10 mg/kg bw per day (rat)					117 weeks ++	117 weeks ++	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.MoaAnalysis.EmpiricalSupport
	MIE	KE1	KE2	KE3	KE4	AO																									
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10 mg/kg bw per day (rat)					117 weeks ++	117 weeks ++																									

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	23 mg/kg bw per day (rat)					24-52 weeks +																	
	31.26 mg/kg bw per day (rat)					26 weeks +	26 weeks +																
	100 mg/kg bw per day (rat)		13 weeks ++		13 weeks ++																		
	200 mg/kg bw per day (rat)			2 weeks ++																			
Conclusion on MoA analysis	<p>The conclusion of the MoA analysis should be presented in a tabular form. In this section, when relevant, comparative MoA analysis can be reported as well.</p> <p>When more than one MoA is postulated, include a conclusion for each MoA postulated.</p> <p>Example: Summary of the MoA analysis</p> <table border="1" data-bbox="349 1354 1079 1743"> <thead> <tr> <th></th> <th>MIE to KE1</th> <th>KE1 to KE2</th> <th>KE2 to KE3/4</th> <th>KE4 to AO</th> </tr> </thead> <tbody> <tr> <td></td> <td>Androgen receptor to decreased testosterone</td> <td>Decreased testosterone to increased LH</td> <td>Increased LH to Leydig cell hyperplasia</td> <td>Leydig tumors</td> </tr> <tr> <td>Biological</td> <td>STRONG: well documented that anti-</td> <td>STRONG: ↓ testosterone induces negative</td> <td>STRONG: LH induces Leydig cells to</td> <td>STRONG: It is known that a continuum exists</td> </tr> </tbody> </table>							MIE to KE1	KE1 to KE2	KE2 to KE3/4	KE4 to AO		Androgen receptor to decreased testosterone	Decreased testosterone to increased LH	Increased LH to Leydig cell hyperplasia	Leydig tumors	Biological	STRONG: well documented that anti-	STRONG: ↓ testosterone induces negative	STRONG: LH induces Leydig cells to	STRONG: It is known that a continuum exists	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoAAnalysis.ConclusionOnMoa
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Biological	STRONG: well documented that anti-	STRONG: ↓ testosterone induces negative	STRONG: LH induces Leydig cells to	STRONG: It is known that a continuum exists																			

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	<p>plausibility</p> <p>androgenic activity leads to ↓ testosterone</p> <p>feedback to hypothalamus to ↑ LH production</p> <p>produce Testosterone. This over time can lead to hyperplasia</p> <p>between epithelial cell hyperplasia and tumors</p>		
	<p>Empirical support</p> <p>WEAK: Dose and time concordance were compromised by the dose selection and study design (selected parameters, hormones, and length of the study)</p> <p>STRONG: dose and temporal concordance observed in several rat studies</p>		
	<p>Essentiality</p> <p>No data</p>		
	<p>Consistency</p> <p>Particularly Leyding cells hyperplasia and tumors have been observed in several studies. Also AR anti-androgenic activity supported by several <i>in vitro</i> assays</p>		
	<p>Analogy</p> <p>Similar effects are known to occur with multiple chemicals acting on the same MIE, including therapeutic drugs.</p>		
	<p>Specificity</p> <p>Although a clear experimental understanding of early KEs is lacking, the sequence of KEs from the MIE to the AO is considered specific</p>		
Uncertainty analysis		Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.UncertaintyAnalysis
Uncertainty analysis	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and those associated with methodology e.g. excluded factors		FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForH

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			umansEasmodality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to the both MoA analysis and assessment of the lines of evidence.	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification	Characterise the overall impact of the source of uncertainty on the assessment conclusion	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForHumansEasmodality.UncertaintyAnalysis.UncertaintyAnalysis.Justification
Uncertainty analysis			
Assessment of ED for non-target organisms (T-modality)		Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality

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Assessment of the lines of evidence		Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence
Have T-mediated parameters been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>T-mediated adversity in non-target organisms</u> has been sufficiently investigated (or not) and the rationale.	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.SufficientInvestigationOnT
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation).	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.EvidenceAdverseEffects
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation).	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssess

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			ment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity
WoE for adversity and endocrine activity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity
Has endocrine activity been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>T-mediated endocrine activity in non-target organisms</u> has been sufficiently investigated (or not) and the rationale..	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated
Selection of relevant scenario	In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrg

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	<p>For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.</p> <p>Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.</p> <p>Example: Selection of relevant scenario</p> <table border="1" data-bbox="358 596 1057 1705"> <thead> <tr> <th data-bbox="358 596 532 785">Adversity based on T-mediated parameters</th> <th data-bbox="532 596 683 785">Positive mechanistic OECD CF level 2/3 Test</th> <th data-bbox="683 596 786 785">Scenario</th> <th data-bbox="786 596 1057 785">Next step of the assessment</th> </tr> </thead> <tbody> <tr> <td data-bbox="358 785 532 947">No (sufficiently investigated)</td> <td data-bbox="532 785 683 947">Yes/No</td> <td data-bbox="683 785 786 947">1a</td> <td data-bbox="786 785 1057 947">Conclude: ED criteria not met because there is not "T-mediated" adversity</td> </tr> <tr> <td data-bbox="358 947 532 1108">Yes (sufficiently investigated)</td> <td data-bbox="532 947 683 1108">Yes/No</td> <td data-bbox="683 947 786 1108">1b</td> <td data-bbox="786 947 1057 1108">Perform MoA analysis</td> </tr> <tr> <td data-bbox="358 1108 532 1289">No (not sufficiently investigated)</td> <td data-bbox="532 1108 683 1289">Yes</td> <td data-bbox="683 1108 786 1289">2a (i)</td> <td data-bbox="786 1108 1057 1289">Perform MoA analysis (additional information may be needed for the analysis)</td> </tr> <tr> <td data-bbox="358 1289 532 1472">No (not sufficiently investigated)</td> <td data-bbox="532 1289 683 1472">No (sufficiently investigated)</td> <td data-bbox="683 1289 786 1472">2a (ii)</td> <td data-bbox="786 1289 1057 1472">Conclude: ED criteria not met because no T-mediated endocrine activity observed</td> </tr> <tr> <td data-bbox="358 1472 532 1705">No (not sufficiently investigated)</td> <td data-bbox="532 1472 683 1705">No (not sufficiently investigated)</td> <td data-bbox="683 1472 786 1705">2a (iii)</td> <td data-bbox="786 1472 1057 1705">Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario</td> </tr> </tbody> </table>	Adversity based on T-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment	No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not " T-mediated " adversity	Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis	No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)	No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no T-mediated endocrine activity observed	No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario	<p>anismsTmodality. AssessmentLinesOfEvidence. SelectionOfRelevantScenario</p>
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	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis		
MoA analysis	<p>The following fields should be completed only for scenarios 1b, 2a(i) and 2b.</p> <p>In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis."</p> <p>Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.</p>				Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis
Postulated MoA	<p>Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be reflected here.</p>					FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa
Name of postulated MoA	<p>Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.</p> <p>.</p>				Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnal

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			ysis.Postulate dMoa.Postula tedMoa
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, ..., AO.	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.Postulate dMoa.EventType
Event description	Description of the event e.g. Change in Thyroid histopathology	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.Postulate dMoa.EventDescription
Supporting evidence	Supporting evidence at the Lowest Observable Adverse Effect Level e.g. Amphibian metamorphosis assay (AMA), 5 mg/l	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.Postulate dMoa.SupportingEvidence
Link to relevant study records	Link to the reference entity for the supporting evidence.	Literature reference list	FLEXIBLE_SUMMARY.EndocrineDisruptingProperties

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			AssessmentP est.EdAssess ment.EdForN onTargetOrg anismsTmod ality.MoaAnal ysis.Postulate dMoa.Releva ntRecords																																			
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	Specificity	This MOA is not very specific and can occur as a consequence of activation of different MIE. However, the upstream KEs are specific of a liver mediated MIE. As such, this MOA is specific.		
Uncertainty analysis			Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality.UncertaintyAnalysis
Uncertainties	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and uncertainty associated with methodology e.g. excluded factors.			FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to the both MoA analysis and assessment of the lines of evidence.		Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsTmodality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification	Characterise the overall impact of the source of uncertainty on the assessment conclusion		Text area	FLEXIBLE_SUMMARY.Endo

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			crineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.UncertaintyAnalysis.UncertaintyAnalysis.Justification
Uncertainty analysis			
Assessment of ED for non-target organisms (EAS-modality)		Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality
Assessment of the lines of evidence		Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence
Have EAS-mediated parameters been sufficiently	Provide an assessment for the following information by specifying if the <u>EAS-mediated adversity in non-target organisms</u> has been sufficiently investigated (or not) and the rationale	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasMo

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investigated?			dality.AssessmentLinesOfEvidence.SufficientInvestigationEas
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation).	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.EvidenceAdverseEffects
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation).	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity
WoE for adversity and endocrine activity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.WoEAdversityEn

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<p>Has endocrine activity been sufficiently investigated?</p>	<p>Provide an assessment for the following information by specifying if the <u>EAS-mediated endocrine activity in non-target organisms</u> has been sufficiently investigated (or not) and the rationale.</p>	<p>Closed list with remarks</p>	<p>EndocrineActivity FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated</p>								
<p>Selection of relevant scenario</p>	<p>In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.</p> <p>For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.</p> <p>Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.</p> <p>Example: Selection of relevant scenario</p> <table border="1" data-bbox="352 1444 1073 1713"> <thead> <tr> <th data-bbox="352 1444 537 1608">Adversity based on T-mediated parameters</th> <th data-bbox="537 1444 691 1608">Positive mechanistic OECD CF level 2/3 Test</th> <th data-bbox="691 1444 797 1608">Scenario</th> <th data-bbox="797 1444 1073 1608">Next step of the assessment</th> </tr> </thead> <tbody> <tr> <td data-bbox="352 1608 537 1713">No (sufficiently investigated)</td> <td data-bbox="537 1608 691 1713">Yes/No</td> <td data-bbox="691 1608 797 1713">1a</td> <td data-bbox="797 1608 1073 1713">Conclude: ED criteria not met because there is not "T-mediated" adversity</td> </tr> </tbody> </table>	Adversity based on T-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment	No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not " T-mediated " adversity	<p>Closed list with remarks</p>	<p>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.SelectionOfRelevantScenario</p>
Adversity based on T-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment								
No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not " T-mediated " adversity								

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	Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis		
	No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)		
	No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no T-mediated endocrine activity observed		
	No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario		
	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis		
MoA analysis	<p>The following fields should be completed only for scenarios 1b, 2a(i) and 2b.</p> <p>In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis."</p> <p>Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.</p>				Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis
Postulated MoA	<p>Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be reflected here.</p> <p>A tabular representation can also be reported here.</p>					FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis

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	If the postulated MoA is a non-EATS MoA, please indicate it after the name of the postulated MoA.		onTargetOrg anismsEasMo dality.MoaAn alysis.Postula tedMoa
Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.PostulatedMoa
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, ..., AO.	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.Event Type
Event description	Description of the event e.g. decrease in VTG level	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.Event Description

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Supporting evidence	Supporting evidence a the Lowest Observable Adverse Effect Level e.g. FSTRA (Fish Short-term reproduction Assay) (0.5 mg/l)	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.SupportingEvidence
Link to relevant study records	Link to the reference entity for the supporting evidence.	Literature reference list	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.RelevantRecords
Postulated MoA			
Empirical support	<p>When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document.</p> <p>Example: Dose- and temporal-concordance between key events of the postulated MoA</p>	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.EmpiricalSupport

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	MIE	KE1 ↓ estradiol level	KE2 ↓ VTG level	KE3 change on gonad histopathology	AO↓ Fecundity			
						Aromatase inhibition <i>in vitro</i> (AC50=29.6µM)		
		++ (3 weeks)	++ (3 weeks)		++ (3 weeks)	0.5 µg/l Fathead minnow		
			+ (36 weeks)	+ (36 weeks)	+ (36 weeks)	0.558 µg/l Fathead minnow		
			+ 3 weeks)		+ (3 weeks)	1 µg/l Fathead minnow		
Conclusion on MoA analysis	<p>The conclusion of the MoA analysis should be presented in a tabular form. In this section, when relevant, comparative MoA analysis can be reported as well.</p> <p>When more than one MoA is postulated, include a conclusion for each MoA postulated.</p> <p>Example Summary of the MoA analysis</p>						Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAn

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	MIE to KE1	KE1 to KE2	KE2 to KE3 Increased LH to	KE to AO		analysis.ConclusionOnMoa
Biological plausibility	STRONG: The link between aromatase inhibition and decrease in estradiol level (E2) is supported by the available knowledge (AOP 25, Villeneuve 2016)	MODERATE – The role of E2 as major regulator of VTG production is well known. Therefore, it can be assumed that a decrease in estradiol level will also lead to a decrease in VTG in plasma.	MODERATE – Based on the available knowledge it is not clear whether a decrease in VTG can lead to the observed histopathology changes in ovary. However, specific gonad histopathology is categorised as 'EAS-mediated' by the OECD GD 150. In addition, the link between VTG level and yolk formation is also supported by the biological knowledge.	STRONG - the link between changes in female gonad histopathology and decreased fecundity is supported by the biological knowledge.		
Empirical support	MODERATE – There is little direct support for dose-response concordance	STRONG – Although the decrease in estradiol and VTG levels were observed at	MODERATE – histopathology changes were measured	STRONG – fecundity was observed		

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	<p>of these key events in vivo. However, using in vitro systems concentrations that reduce aromatase activity tend to elicit reductions in estradiol production.</p>	<p>the same concentrations, this can be scientifically explained by a number of factors (e.g. dose spacing in the test system; higher variation in VTG concentration in plasma than in circulating steroids)</p>	<p>only in longer term study and only observed at the highest tested concentration. The VTG decrease was observed at the same concentration. However, this can be due to the dose spacing and tested concentrations</p>	<p>erved at the same concentration as histopathology changes and above.</p>		
	Essentiality	MODERATE- No data are available to support the assessment of essentiality. However, the available knowledge and validated AOP (25) supports the essentiality of key events.				
	Consistency	The KEs have been observed consistently in three different studies with different duration. The pattern of effects is consistent between the studies; there are no conflicting observations. Consistency across species cannot be assessed because there are only studies on one species.				
	Analogy	Aromatase inhibition is well established for compounds belonging to the same chemical class.				
	Specificity	Liver histopathology changes observed in one study at the highest tested concentration where other effects were also observed. However, the positive indication of endocrine activity from various studies and cell lines allowed to exclude a non-ED MOA.				
Uncertainty analysis					Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssess

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			ment.EdForNonTargetOrganismsEasModality.UncertaintyAnalysis
Uncertainty analysis	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and those associated with methodology e.g. excluded factors		FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to the both MoA analysis and assessment of the lines of evidence.	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification	Characterise the overall impact of the source of uncertainty on the assessment conclusion	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.EdAssessment.EdForNonTargetOrganismsEasModality.UncertaintyAnalysis.UncertaintyA

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			nalysis.Justification
Uncertainty analysis			
Overall conclusion ED assessment	Report under this section whether the ED criteria are met according to Regulation EU 2018/605.	Header 1	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.OverallConclusionEdAssessment
Overall conclusion ED assessment for humans		Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.OverallConclusionEdAssessment.OverallConclusionEdAssessmentHumans
Does the substance meet the ED criteria for humans?	Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for humans? Provide the reasoning behind the conclusion.	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.OverallConclusionEdAssessment.OverallConclusionEdAssessmentHumans.CriteriaForHumansMet
Overall conclusion ED assessment for non-target organisms		Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.OverallConclusionEdAssessment.OverallConclusion

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			onEdAssessm entNonTarge tOrganisms
If ED criteria are met for humans, is the adverse effect identified relevant for wild mammals' population?	<p>When replying this question, explain the relevance at population level of the adverse effect(s) observed in the dataset for concluding on the ED criteria for humans.</p> <p>Provide the reasoning behind the conclusion.</p>	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms.AdverseEffectRelevantForMammals
Does the substance meet the ED criteria for wild mammals?	<p>Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for wild animals?</p> <p>Provide the reasoning behind the conclusion.</p>	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms.EdCriteriaMammalsMet
Does the substance meet the ED criteria for non-target organisms other than wild mammals?	<p>Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for non-target organisms other than wild mammals?</p> <p>Provide the reasoning behind the conclusion.</p>	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPEst.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms.I

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<p>Additional information</p>	<p>Discussion(Header 1) – common block</p> <p>Provide any additional information to support this assessment of endocrine disrupting properties</p> <p>Upload the Excel file, in the format for reporting the available information specified in the guidance (this excel file will be published). Appendix E.1 to the Guidance (https://doi.org/10.2903/j.efsa.2018.5311)</p>	<p>Header 1</p>	<p>Impact on Other Organisms</p> <p>FLEXIBLE_SUMMARY.Endocrine Disrupting Properties Assessment Presentation</p>
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Link to support material:

ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018.

Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311, 135 pp.
<https://doi.org/10.2903/j.efsa.2018.5311>. [ECHA-18-G-01-EN](#)

EFSA Scientific Committee (2017) Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971

OECD Series on Testing and Assessment: No 150: Guidance document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption. ENV/JM/MONO(2012)22, 524 pp

EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132

Workshop report on OECD countries activities regarding testing, assessment and management of endocrine disruptors. Series on testing and assessment No 118. 18 January 2010.

OECD Series on Testing and Assessment: No 148: Guidance document on the androgenised female stickleback screen

Guidance on Uncertainty Analysis in Scientific Assessments, 10.2903/j.efsa.2018.5123

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5.8.3 Endocrine disrupting properties (includes ecotoxicity studies on terrestrial vertebrates) – Endpoint study record

Purpose:

If there is evidence that the active substance may have endocrine disrupting properties, additional information or specific studies shall be required: — to elucidate the mode/mechanism of action, — to provide sufficient evidence for relevant adverse effects. Studies required shall be designed on an individual basis and taking into account Union or internationally agreed guidelines, in the light of the particular parameters to be investigated and the objectives to be achieved.

ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening - v.4.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 229, OECD 230, OECD 231, OECD 234.	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods
Test type		Text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestAnimals

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State	Select as appropriate.	Close list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestAnimals.State
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Details on route of administration	For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of the oral route and method of administration.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnRouteOfAdministration
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on oral exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. The use of an aqueous solution/suspension should be considered first and the most common approach is to use a solution/suspension in oil (e.g. corn, peanut, sesame or olive oil). However, as these oils have different caloric and fat content, thus the vehicle might affect total metabolizable energy (ME) intake.	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnOralExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Close list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on	For robust study summaries or as requested by the regulatory programme, include a short description on	Text area	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMa

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<p>analytical verification of doses or concentrations</p>	<p>the method of analysis. State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable.</p> <p>If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis.</p> <p>If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.</p> <p>It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.</p>		<p>mmlianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations</p>
<p>Duration of treatment / exposure</p>	<p>Indicate duration in days, e.g. '7 days'.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure</p>
<p>Frequency of treatment</p>	<p>Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment</p>
<p>Doses / concentrations</p>	<p>Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.</p>		<p>ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DosesConcentrations</p>
<p>Dose / conc.</p>	<p>Enter numeric value.</p>	<p>Unit measure with Open</p>	<p>ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Administr</p>

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		List (Decimal)	ationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. If not available from picklist, select 'other' and specify. Copy field if more than one type of control was used.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

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	<p>as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
Positive control	<p>Uterotrophic Bioassay: Indicate data from the Baseline Positive Control Test and periodic positive control data (reference oestrogen: 17α-ethinyl estradiol).</p> <p>Hershberger Bioassay: Indicate that a reference androgen agonist (Testosterone Propionate) or a reference androgen antagonist (Flutamide) have been used.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.ExaminationsObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	<p>Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as</p>	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.SacrificeAndPathology

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	appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion
Endocrine disrupting potential	Indicate the endocrine disrupting potential derived from the test results. If positive or ambiguous, include dose(s) / concentration(s) in the supplementary remarks field or representative table. Upload predefined or other appropriate table(s) if any in the rich text field 'Any other information on results incl. tables' and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '...see Table 1')	Close list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.EndocrineDisruptingPotential
Maximum tolerated dose level exceeded	Indicate whether the maximum tolerated dose has been exceeded or not with respect to the endocrine disrupting potential specified in the previous field. This is in particular relevant if the no positive potential has been found.	Close list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.MaximumToleratedDoseLevelExceeded
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.Result

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			sAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.Result sAndDiscussion.EffectLevels
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.Result sAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ApplicantSummaryAndConclusion

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5.8.4 Intermediate effects - mechanistic information

Purpose

This OECD Harmonised Template (OHT) aims to collect non-apical observations obtained from methods such as *in vitro* testing or from other classes of methods (e.g. *ex vivo* or *in silico* methods) providing mechanistic information, i.e. effects on molecular, subcellular, cell, tissue or organ level that can be relevant to the hazard assessment (e.g. through Defined Approaches, Integrated Approaches on Testing and Assessment, as part of weight of evidence and are underpinned by Adverse Outcome Pathways).

In the area of pesticides this OHT can be used for example to:

- 1) Report level 1 and level 2 data and studies of the conceptual framework for testing and assessment of endocrine disruptors submitted for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.
- 2) Mechanistic information relevant for understanding the mode of action of tumour formation if applicable.

Reporting apical vs mechanistic knowledge using OECD Harmonised Templates

In the context of chemical hazard and risk assessment, two classes of knowledge are relevant:

Apical Knowledge	Mechanistic Knowledge
Knowledge about traditional, directly measured whole-organism outcomes of exposure in <i>in vivo</i> tests, generally death, reproductive failure, tumour formation, skin/eye irritation, skin/respiratory sensitisation or developmental dysfunction.	Knowledge about the sequence of events leading from the exposure to an effective dose of a chemical to the production of a specific biological response in the target organ, in most cases measured in non-in-vivo tests.
<i>"One in-vivo test tells us whether an adverse outcome has been observed or not."</i>	<i>"A series of tests, mainly non-animal, tells us why an adverse outcome is likely to manifest itself or not."</i>

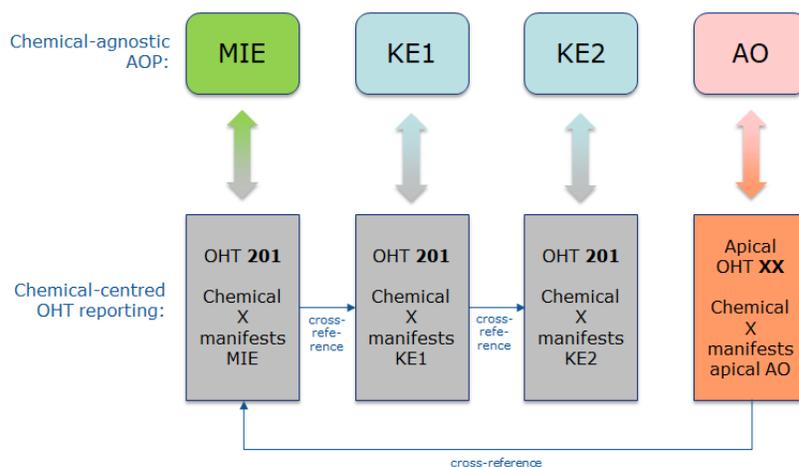
OECD Harmonised Templates allow reporting both kinds of knowledge, if available, and they can complement each other.

Report apical knowledge ... ↓↓↓	Report mechanistic knowledge ...	
For effects on biotic systems, use: OHTs 41 to 57	<i>In a regulatory context: If Mechanistic Knowledge was generated according to an OECD</i>	<i>In all other cases</i>

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For health effects, use: OHTs 58 to 84 & 86	<i>Test Guideline for which an (apical) endpoint OHT²⁰ was created</i> ↓↓↓	↓↓↓
	Use the suitable endpoint OHT, and there, use the mechanism-oriented fields, if available, else use appropriate other fields.	Use OHT 201

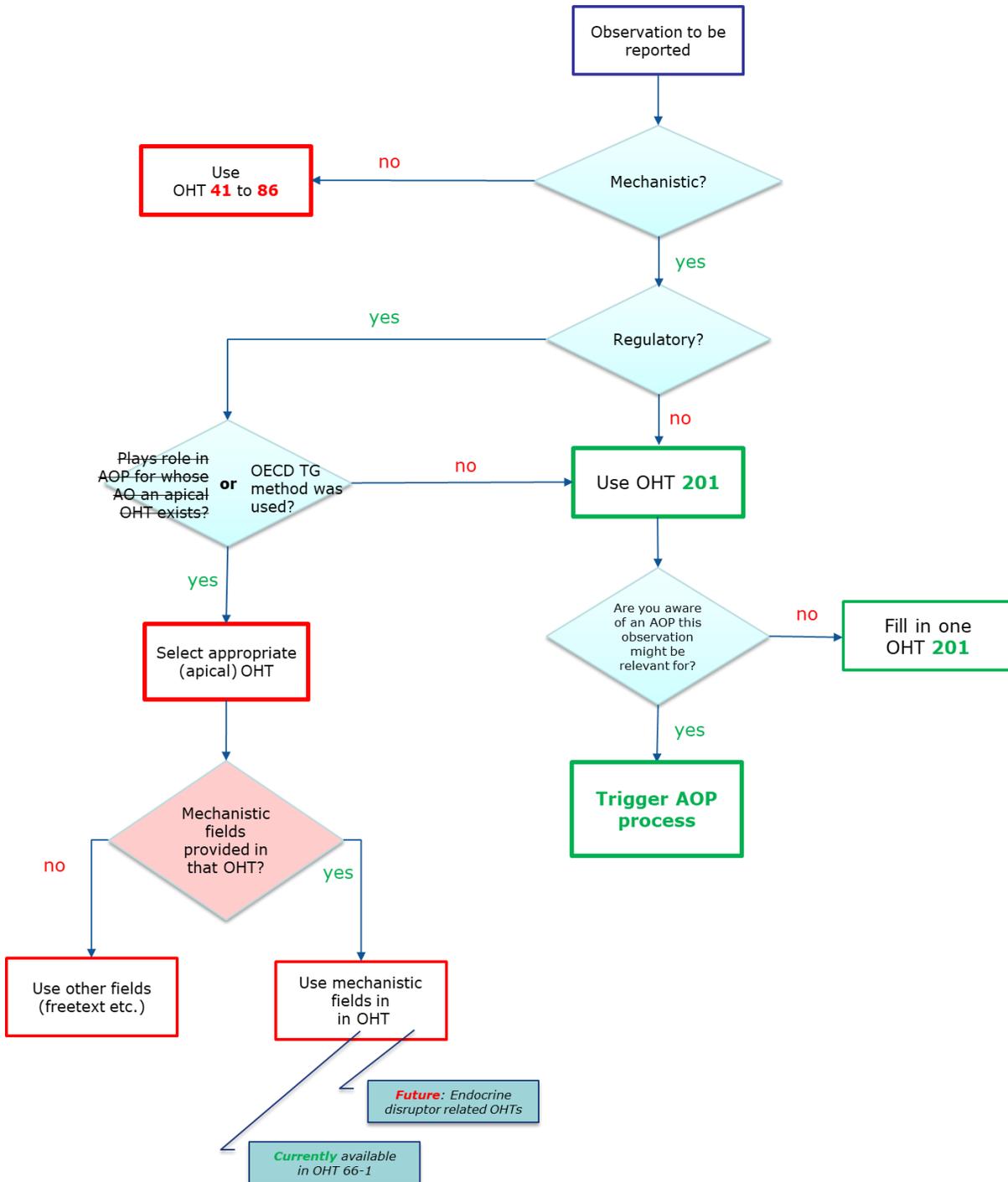
If **OHT 201** is used, it is possible to depict (part of) an AOP by reporting individual observed Intermediate Effects as manifestations of an AOP Key Event:



²⁰ Example: future endocrine disruptor related TG methods

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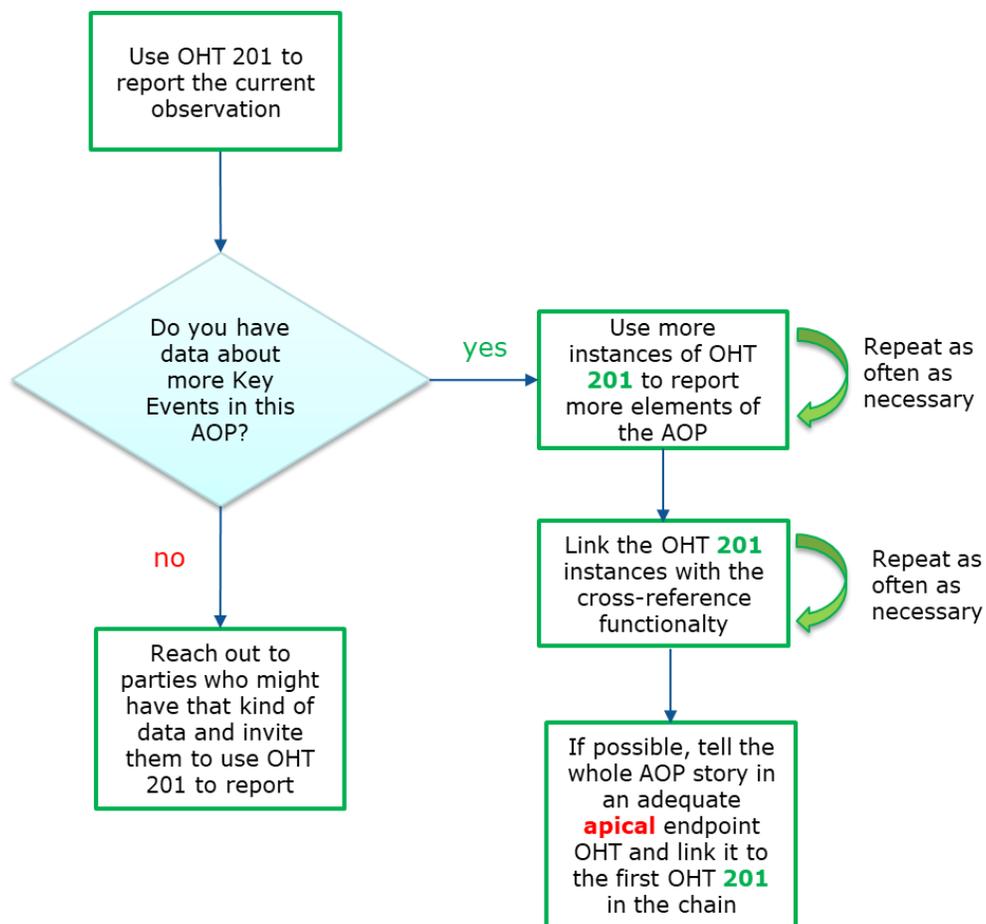
Overview Flowcharts



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See next page for "AOP Process"

AOP Process



Fields to be completed

FLEXIBLE_RECORD.IntermediateEffects v.5.0 (Final) [June 2021]		
Field name	Instructions	Field Path
Administrative data		FLEXIBLE_RECORD.IntermediateEffects.AdministrativeData

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	Confidentiality	FLEXIBLE_RECORD.Intermediate Effects.AdministrativeData.Data Protection
Reason / purpose for cross-reference	<p>Picklist: Select the appropriate reason of the cross-reference, i.e.:</p> <ul style="list-style-type: none"> - adverse outcome pathway (AOP) (in case the mechanistic information is related to a key event that is part of an AOP). Consult the AOP wiki at: https://aopwiki.org) and provide the reference in the remarks field - assessment report (for referring to a record that contains an assessment report as attachment) - defined approach for combining with results from another in vitro method - reference to other assay used for mechanistic information derivation (for optional indication in a study summarising if reference is made to the outcome of another assay) - reference to same study (e.g. if different test systems/in vitro models were used and the results recorded in different records, or different test materials were assessed in the same study, using common reference and control items) - reference to other study (e.g. if another study provides mechanistic information or key event relevant for the same 	FLEXIBLE_RECORD.Intermediate Effects.AdministrativeData.Cross Reference.ReasonPurpose

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	<p>Adverse Outcome Pathway or if another study is considered relevant in the interpretation of the test results)</p> <p>- other: (to be specified)</p>	
Cross-reference		
Study objective(s) / purpose / aim	<p>Specify the objective, purpose and/or aim of the study explaining clearly why the study was performed and what (regulatory) question is answered. For example:</p> <ul style="list-style-type: none"> - determination of skin sensitising properties of the test chemical by measurement of CD54 and CD86 expression in THP-1 cells after exposure to the CV75 concentration. - gather information on mode of action. - derive a point of departure. 	FLEXIBLE_RECORD.Intermediate Effects.AdministrativeData.Study Objectives
Effect identification	<p>The effect has to be identified by providing a 'Process', 'Object' and 'Action'. As a minimum, the 'Process' and 'Action' or the 'Object' and 'Action' must be identified. More than one combination can be provided (e.g. Cell Activation, CD54 molecule, increased & Cell Activation, CD86 molecule, increased). If both Process and Object are provided they have to be concordant with the chosen Action (e.g. both process and object are increased or decreased).</p> <p>See Yves et. al (2017) https://www.liebertpub.com/doi/10.1089/aivt.2017.0017 and the website https://aopwiki.org/</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification

	<p>for the concept and its implementation in practice, respectively.</p> <p>If no suitable terms are available in picklist for Process and Object, please select 'Other' and introduce a new ontology-based term. Please consult the Ontology Lookup Service (OLS) to retrieve the terms that best describe the mechanisms you are reporting. OLS is a repository of the latest versions of biomedical ontologies and it is available at https://www.ebi.ac.uk/ols/index (Jupp S. et al. (2015) A new Ontology Lookup Service at EMBL-EBI. In: Malone, J. et al. (eds.) Proceedings of SWAT4LS International Conference 2015).</p> <p>For each effect identified with a process, object and action (P/O/A), the results can be reported in the reporting section.</p> <p>Please use the following P/O/A for existing OECD test guidelines and methods.</p> <p>TG442C, DPRA and ADRA:</p> <p>protein binding / - / increase</p> <p>TG442D, Keratinosens:</p> <p>keratinocyte activation / aldo-keto reductase family 1 member C2 (AKR1C2) / increase</p> <p>TG442D, Lusens:</p> <p>keratinocyte activation /</p>	
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	<p>NAD(P)H dehydrogenase [quinone] 1 (NQ01) / increase</p> <p>TG442E, h-CLAT:</p> <p>cell activation / CD54 molecule (intercellular adhesion molecule 1) / increase</p> <p>and</p> <p>cell activation / CD86 molecule / increase</p> <p>TG442E, U-SENS:</p> <p>cell activation / CD54 molecule (intercellular adhesion molecule 1) / increase</p> <p>TG442E, IL8 LUC:</p> <p>cell activation / interleukin 8 (IL8) / increase</p> <p>TG455, ERTA STTA, VM7Luc and ERα CALUX:</p> <p>nuclear receptor activity / estrogen receptor alpha / increase, agonism</p> <p>and</p> <p>nuclear receptor activity / estrogen receptor alpha / decrease, antagonism</p> <p>TG456, H295R Steroidogenesis Assay:</p> <p>steroid hormone biosynthetic process / estradiol / alteration</p> <p>and</p>	
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	<p>steroid hormone biosynthetic process / testosterone / alteration</p> <p>TG458, ARTA STTA, AR-CALUX and 22Rv1/MMTV GR-KO:</p> <p>nuclear receptor activity / androgen receptor / increase, agonism</p> <p>and</p> <p>nuclear receptor activity / androgen receptor / decrease, antagonism</p> <p>TG493, hrER binding FW assay and CERI assay:</p> <p>Nuclear receptor binding / estrogen receptor alpha / binder–non binder</p>	
P/O/A details		FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Details
Process	<p>Picklist: Process represents the dynamics of the underlying biological system (e.g., receptor binding) (Ives et al, 2017). The Process is also used to annotate Key events in the Adverse Outcome Pathway Wiki (https://aopwiki.org/) as described in Ives et al, 2017, doi:10.1089/aivt.2017.0017).</p> <p>Select the process that best describes the mechanistic information observed or select 'other' to specify the Process and provide a term. Please consult the Ontology Lookup Service (OLS) which is available at https://www.ebi.ac.uk/ols/index</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Details.Process

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	<p>to choose a Process term. If possible please select as Process one term belonging to the following ontology Gene Ontology (GO).</p> <p>For most terms there will be several options. It is therefore important to also copy the preferred ontology identifier into the remarks field.</p> <p>Cytotoxicity data should only be reported as a process (e.g. cell death) when it is the scope of the study to determine cytotoxicity. In cases where cytotoxicity is measured for supporting information e.g. for dose selection/elimination, it should not be considered as a process. Such data are reported as 'Other observations'.</p>	
<p>Object</p>	<p>Picklist: Object represents the subject of the (biological) effect observed, for example, a specific biological receptor that is activated or inhibited The Object is also used to annotate Key events in the Adverse Outcome Pathway Wiki (https://aopwiki.org/) as described in Ives et al, 2017, doi:10.1089/aivt.2017.0017).</p> <p>It is optional to record both Process and Object. If both Process and Object are recorded they have to be concordant with the chosen Action.</p> <p>Select the object that best describes the subject of the effect observed or select 'other' to specify the Object and provide a term. Please consult</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Details.Object</p>

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	<p>the Ontology Lookup Service (OLS) which is available at https://www.ebi.ac.uk/ols/index to choose a Process term. If possible please select as Object one term belonging to the following ontologies protein Ontology (PR) or Chemical Entities of Biological Interest (ChEBI).</p> <p>For most terms there will be several options. It is therefore important to also copy the preferred ontology identifier into the remarks field.</p> <p>More than one object can be provided e.g. when changes of more than one biomarker is measured.</p>	
<p>Action</p>	<p>Picklist: Action represents the type of effect observed e.g. "decrease" in the case where a receptor is inhibited to indicate a decrease in the signalling by that receptor. Action is also used to annotate Key events in the Adverse Outcome Pathway Wiki (https://aopwiki.org/) as described in Ives et al, 2017, doi:10.1089/aivt.2017.0017). Action is used together with the field Process and/or Object.</p> <p>The Action field is always required to describe the effect observed and it can form the following syntaxes "Process, Action" e.g. "gene expression, increase" or "Process, Object, Action" e.g. receptor activity, estrogen receptor, increase.</p> <p>Select the Action that best describes the effect observed or</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Details.EffectAction</p>

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	select 'other' to specify the action and provide a term	
P/O/A details		
Details on effect identification	Enter any relevant details concerning the Effect Identification. E.g. in case of selection of more than one triplet for "Process, Object, Action" or when a meaningful term was not found.	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Effect Details
Context	<p>This repeatable block of fields allows for indicating in which target system (on organ level) the observed effect(s) play a role. This may be used in the AOP / MOA building as appropriate.</p> <p>Copy this block of fields for referring to different target systems if applicable. For a given system, multiple organs can be selected.</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Context
System	Picklist: Select the specific system where the observed effect(s) play a role. More than one 'Context' item can be created.	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Context.System
Organ	<p>Picklist: Select from the multiple drop-down list the target organ(s) addressed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.</p> <p>Guidance for field condition: Conditional picklist</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Context.Organ
Remarks	Include any remarks as appropriate.	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Context.Remarks
Context		
Materials and methods		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods

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Test system		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem
Type of test system	<p>Picklist: A test system is any biological, chemical or physical system or a combination thereof used in a study (OECD (2018), Guidance Document on Good In Vitro Method Practices (GIVIMP), OECD Series on Testing and Assessment, No. 286, OECD Publishing, Paris).</p> <p>Examples of physical chemical based test systems: serum protein, peptide, enzyme.</p> <p>Select complex biological test system for example in case of: 3D model, induced pluripotent stem cells, organ on a chip, co-cultures, etc.</p> <p>Select 'other:' in case you don't find a suitable option, for example when your test system is a test kit or a lower in vivo organism.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.TestSystemType
Test system identity	<p>Picklist: The test systems listed are those from existing test guidelines. Select the test system used or select other and provide the test system identity. Furthermore, provide information on:</p> <ul style="list-style-type: none"> - Source / supplier - Catalogue / batch number - Species and strain (as relevant) of the origin of the test system. <p>In case a co-culture of cell lines is used, or S9 mix or</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.TestSystemIdentity

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	<p>microsomes are used in combination with a cell line, the user is asked select 'other' and to provide the identity of all components under 'remarks'. In the later fields for 'details on the test system' and 'metabolic competence' the test system can be further described.</p>	
Genetic modification of the test system	<p>Picklist : When applicable, provide the following information on the genetic modification:</p> <ul style="list-style-type: none"> - Gene inserted - Gene species (e.g. human, rat, mouse) - Additional information on modification 	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.GeneticModOfSystem
Details of the test system	<p>Freertext template: TEST SYSTEM DESCRIPTION</p> <p>Provide a short description of the test system, including (species, organ, tissue or cell type (e.g. human monocytoc leukemia cell line or human cryopreserved pooled liver tissue homogenate 9000 g fraction (S9):</p> <p>For cell lines:</p> <ul style="list-style-type: none"> - Number of passages used, if applicable: - Cell cycle length, doubling time or proliferation index: - Measures taken for avoiding or screening for contamination by mycoplasma, bacteria, fungi and virus - Periodically checked for karyotype stability: [yes/no] - Differentiation performed 	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.TestSystemDetails

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	<p>[yes/no], describe:</p> <p>MEDIA USED and incubation conditions</p> <ul style="list-style-type: none"> - Type and composition of media, including use of serum and antibiotics: - Incubation conditions such as CO2 concentration, humidity level, temperature, if applicable: 	
Metabolic competence of the test system	<p>Picklist: Select the option that fits best and describe the knowledge about the metabolic competence (i.e. Phase I and/or II biotransformation capacity) of the test system under remarks.</p> <p>For example, when the test system used is cryopreserved human pooled liver tissue homogenate 9000 g fraction (S9) procured from a commercial supplier, select "metabolic activity, specify" and specify:</p> <p>contains phase I and II metabolic enzymes present in the microsomal (e.g. cytochrome P450s, Flavin-containing monooxygenase, uridine 5'-diphospho-glucuronosyltransferases, carboxylesterases) and cytosolic (e.g. sulfotransferases, glutathione S-transferases, methyltransferases, N-acetyl transferases, xanthine oxidase, aldehyde oxidase) fractions.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.MetabolicCompetence
Detection method		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.DetectionMethod
Detection method used	Picklist: Indicate the readout used. Select a detection method type from the picklist and	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.Det

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	<p>provide the type of instrument (e.g. HPLC, Spectrophotometer, Flow cytometer) or chose 'other:' and specify the type or equipment used / analysis performed.</p>	<p>ectionMethod.DetectionMethodUsed</p>
<p>Details on detection method</p>	<p>Quantitative analytical methods:</p> <p>'Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. "parent compound", "parent and transformation products" or "transformation product:") in matrices. Use free text template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report.</p> <p>Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms "data collection method" and "enforcement method" see help text for field "Instrument / detector".</p> <p>Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Freetext template:</p> <p>Option 1 Option 1: Semi or non-quantitative detection methods SEMI OR NON-QUANTITATIVE DETECTION METHODS</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.DetectionMethod.DetailsOnDetectionMethod</p>

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	<p>Instrument type and model:</p> <p>Option 2 Option 2: Quantitative analytical methods QUANTITATIVE ANALYTICAL METHODS</p> <p>Instrument type and model:</p> <p>COMPOUND (ANALYTE): ...</p> <ul style="list-style-type: none"> - Method ID: - Extraction solvent/technique: - Cleanup strategies: - Derivatisation (if any): - Instrument/detector (if further details): - Standardisation method: - Stability of standard solution: - Retention times: - Detection limit (Limit of Quantification) - Other: <p>INTERFERING SUBSTANCE(S):</p> <p>STABILITY OF PARENT AND TRANSFORMATION PRODUCTS AT VARIOUS STAGES OF ANALYSIS:</p> <p>PROBLEMS / PRECAUTIONS:</p> <ul style="list-style-type: none"> - Special problems encountered: - Precautions to be taken during: <ul style="list-style-type: none"> - analysis of samples: - handling of samples: - storage of samples: <p>TOTAL TIME FOR COMPLETION:</p>	
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Test design		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign
Test material preparation		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.TestMaterialPreparation
Concentration selection of the test material	<p>Picklist: For data interpretation it is important to know on what basis the highest concentration tested was selected.</p> <p>Prior information of response and interference with the test system can e.g. be obtained through literature or with experimental data in a dose-range finding experiment.</p> <p>Example for TG442E (h-CLAT)</p> <p>Highest concentration to be used is either of the following concentrations:</p> <ul style="list-style-type: none"> - 1.2-fold the CV75 concentration of the test chemical, i.e. the concentration where 25% of the cells is dead. - Maximum 5000 µg/mL for non-cytotoxic test chemicals that dissolve or stably disperse in the solvent saline and subsequently in medium. - Maximum 1000 µg/mL for non-cytotoxic test chemicals that dissolve in DMSO and subsequently in medium. <p>Any free text explanation can be given in the adjacent text field to justify the dose level selected.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.TestMaterialPreparation.ConcentrationSelection
Vehicle / solvent	Picklist: If a vehicle or solvent was used, select the relevant	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.Te

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	<p>item or use 'other:' and specify. You can give further relevant information in the supplementary remarks field, e.g. lot/batch no., purity, concentration, etc.</p> <p>In case a solvent is used that is different from those recommended in the in vitro method Standard Operating Procedure or test guideline, a justification for the choice must be provided.</p>	<p>stDesign.TestMaterialPreparation.Vehicle</p>
<p>Dilution steps / dose intervals</p>	<p>Indicate if the test material was further diluted before exposure of the test system. In case of dose range, provide the amount of concentrations and dilution factor.</p> <p>Example description: The test material was first diluted in 70% ethanol and subsequently diluted 500-fold in cell culture medium. Another 2-fold dilution was executed in the well to obtain a total of 1000-fold dilution and a final solvent concentration of 0.07%. Freetext template: DILUTION STEPS PERFORMED</p> <p>Provide the following information (where available):</p> <ul style="list-style-type: none"> - Dilution steps from 'stock solution' in the vehicle/solvent including the final % of vehicle/solvent in the exposure medium - Dose intervals in case of dose range - Number of concentrations prepared 	<p>FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.TestMaterialPreparation.DilutionStepsDoseIntervals</p>

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Control and reference items		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems
Controls / reference items used	Indicate whether controls / reference substances were used. If 'yes' is selected, the details can be entered in the repeatable block 'Controls / reference substances'.	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceItemsUsed
Controls / reference items	<p>Indicate whether solvent/vehicle controls, negative controls, true negative controls (i.e. negative reference substances) and/or positive controls (i.e. positive reference substances) were tested concurrently. Repeat this block of fields as necessary.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide information in the supplementary remarks field, e.g. to the identity, supplier, lot and purity of the control substance(s) and the concentration / amount applied.</p> <p>Guidance for field condition: Condition: Block of fields active only if 'Controls / reference substances used' is 'yes'</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances
Type of controls used	<p>Picklist: Select the type of control used to demonstrate the proper performance of the test system and therefore the validity of the experiments. More than one control/reference item can be provided.</p> <p>See (GIVIMP, OECD guidance document 286 in the series on testing and assessment).</p> <p>Solvent / vehicle controls consist</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances.TypeOfControls

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	<p>of solvent or vehicle alone, without test item (test material), and otherwise treated in the same way as the treatment groups.</p> <p>Negative / untreated controls consist of culture medium without solvent / vehicle or test item, and otherwise treated in the same way as the treatment groups.</p> <p>True negative controls include items (e.g. chemicals) with known lack of activity.</p> <p>Positive controls include items with known activity.</p> <p>Reference items are substances with known activity, used as basis for comparison with the test item (test material).</p>	
Description of reference and control items used	<p>Picklist: Select the reference or control item used or provide the name and identifier (e.g. CAS number), and in the remarks field the purity and concentration (range) used.</p> <p>If 'other:' is selected, provide the name and identity (CAS number) in the additional text field.</p> <p>For each selection (including the 'other:'), provide purity (%) and concentration (range or single concentration) in the field 'Remarks'.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances.ControlOrReferenceItemsUsed
Remarks	Additional information, such as solvents used.	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances.Remarks

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Controls / reference items		
Experimental conditions		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ExperimentalConditions
Number of replicates	<p>Provide the number of replicates per concentration and the number of independent experiments performed. For each experiment, valid or invalid, results should be reported.</p> <p>NUMBER OF REPLICATIONS:</p> <ul style="list-style-type: none"> - Number of replicates per concentration (single, duplicate, triplicate) - Number of independent experiments 	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ExperimentalConditions.NumberOfReplicates
Experimental conditions	<p>Use free text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009; OECD Programme, Pesticides NAFTA or EU REACH) thereof.</p> <p>Concentration of biological test systems is usually expressed as cell density (amount of cells/cm² or cells/ml seeded) or confluence (%).</p> <p>Concentration of physical chemical test systems is usually expressed in mg/ml or molarity.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ExperimentalConditions.ExperimentalConditions

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	<p>Incubation conditions are e.g. temperature, CO₂, concentration, humidity level, etc.</p> <p>A vessel can e.g. be a test tube or cell culture plates with 24, 96 or 384 wells.</p> <p>Freetext template: METHOD OF TREATMENT/ EXPOSURE:</p> <ul style="list-style-type: none"> - Concentration of the test system (e.g. cell density or number of cells used) - Description how the test material was added to the test system (e.g. in medium, in suspension) <p>TREATMENT AND HARVEST SCHEDULE:</p> <ul style="list-style-type: none"> - Pre-incubation period, if applicable - Exposure duration / duration of treatment - Frequency of administration, e.g. single, repeated or continuous - Harvest time after the end of treatment (sampling/recovery times) - Incubation conditions - Vessel type used for exposure <p>- OTHER:</p>	
<p>Additional analysis: e.g. cytotoxicity assay or other</p>	<p>Picklist: This picklist was established on basis of GIVIMP annex I (OECD, 2018).</p> <p>Select the viability assay used to measure cytotoxicity:</p> <p>Select 'other cytotoxicity assay'</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ExperimentalConditions.AdditionalAnalysis</p>

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	<p>in case another type of cytotoxicity assay was used. Select 'other type of analysis' in case another or another type of analysis was performed that is important for the interpretation of results (e.g. pH, autofluorescence, etc.).</p> <p>In the remarks field any additional information can be provided.</p>	
Data analysis		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.DataAnalysis
Acceptance criteria for the test material results	<p>Acceptance criteria: Criteria for when results can be accepted, i.e. a set of well-defined parameters describing aspects of the method such as range for positive and negative controls (GIVIMP, OECD, 2018).</p> <p>For cell-based methods, the acceptance criteria should include the level of cytotoxicity or other type of interference that is accepted / not accepted.</p> <p>Any free text explanation can be given to specify which criteria exist for acceptance of results, e.g. related to reference and control substances or vehicle/solvent control, cytotoxicity or other interference, capturing of full dose-response, minimum/maximum response to be observed or outliers.</p> <p>Freetext template: Provide a description or list of the study acceptance criteria:</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.DataAnalysis.AcceptanceCriteria
Data calculation and statistics	Provide the method used to calculate the results from raw data to the parameters	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.DataAnalysis

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	<p>calculated, such as normalisation, use of calibration curve, subtraction of control values, calculation of averages, Standard deviations etc.</p> <p>List the statistical methods used to derive the parameters to be reported. Include a statement on the appropriateness of the statistical analysis used. Parameters, their explanation and values should be provided in the "Test results" section.</p> <p>Example of data calculation and statistical analysis performed:</p> <p>Relative Light Units raw data were copied to commercially available software Graphpad Prism for hill curve fitting (variable slope, four parameters). Subsequently, the EC50 value and its CV were calculated.</p> <p>Specify if outlier analysis is performed and what (statistical) method was used to exclude values.</p> <p>Calculations performed</p> <ul style="list-style-type: none"> - Statistical methods used - Where relevant, provide the method used to exclude outliers. 	<p>stDesign.DataAnalysis.DataCalculationAndStatistics</p>
<p>Evaluation / data interpretation criteria</p>	<p>Describe the evaluation criteria used in the study to judge if the test material is positive, negative or equivocal. For example:</p> <p>When there is more than 10% binding to the androgen receptor (as expressed in relative light units) for more than two concentrations, the</p>	<p>FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.DataAnalysis.EvaluationDataInterpretationCriteria</p>

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	<p>result is 'positive'.</p> <p>h-CLAT: When the RFI of CD86 is equal to or greater than 150% in at least one tested concentration (with cell viability \geq 50%), the result for the test material is positive. The EC150 value is calculated where possible.</p> <p>DPRA: The mean of cystein and lysine depletion is: Less than 6.38%: minimal reactivity.</p> <p>Between 6.38% and 22.62%: low reactivity</p> <p>Between 22.62% and 42.47%: moderate reactivity.</p> <p>More than 42.47%: high reactivity.</p> <p>Consider also precipitation and co-elution.</p> <p>Evaluation / data interpretation criteria: - Results will be expressed as:</p>	
<p>Any other information on materials and methods incl. tables</p>		<p>FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables</p>
	<p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation</p>

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	<p>upload any htm or html document.</p> <p>Here you may for example provide details on specific material or reagents used. In case of TG442E, h-CLAT you could provide the information on the type of antibodies used, as these are essential components of the method.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	
Results and discussion		FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion
Test results		
Test results	<p>Report the parameters obtained and effective concentration(s) for the type of effect specified in the 'Test results' fields. Copy this field block for entering more than one experiment if necessary, e.g. for a test guideline or if different concentration ranges were tested.</p> <p>One experiment may include more than one replicate for each tested concentration. An independent experiment is usually carried out with independently prepared controls, test system, reagents used for analysis and on a different time.</p> <p>Set this flag if a key observation should be identified for the conclusion section.</p>	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults

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<p>Details of the effect identification</p>	<p>Select the relevant item of effect identification details indicated under 'Details'.</p> <p>Remarks: Dynamic picklist values: - Process / Object / Action (combination 1) - Process / Object / Action (combination 2) - ...</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.DetailsOfTheEffectIdentification</p>
<p>Key result</p>	<p>Set this flag if a key observation should be identified for the conclusion section.</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.KeyObservation</p>
<p>Concentration selection of the test material</p>	<p>Picklist: For data interpretation it is important to know on what basis the highest concentration tested was selected.</p> <p>Prior information of response and interference with the test system can e.g. be obtained through literature or with experimental data in a dose-range finding experiment.</p> <p>Example for TG442E (h-CLAT)</p> <p>Highest concentration to be used is either of the following concentrations:</p> <ul style="list-style-type: none"> - 1.2-fold the CV75 concentration of the test chemical, i.e. the concentration where 25% of the cells is dead. - Maximum 5000 µg/mL for non-cytotoxic test chemicals that dissolve or stably disperse in the solvent saline and subsequently in medium. - Maximum 1000 µg/mL for non-cytotoxic test chemicals that 	<p>FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.ConcentrationSelection</p>

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	<p>dissolve in DMSO and subsequently in medium.</p> <p>Any free text explanation can be given in the adjacent text field to justify the dose level selected.</p>	
Concentration range tested	<p>Indicate the lowest and highest concentration tested.</p> <p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.ConcentrationRangeTested
Number of replicates and outliers	<p>Specify the number of replicates per concentration and if any values were excluded after outlier analysis.</p> <ul style="list-style-type: none"> - Number of replicates: - Information on outlier removal: - Impact of outlier removal on the results: 	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.NumberOfReplicatesAndOutliers
Parameter and result		FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.ParameterAndResult
Parameter	<p>Picklist : This picklist displays either the parameters specific to the selected method, or general parameters in case another method is used.</p> <p>Provide the relevant parameters, representative of the effect measured, that are calculated for your method. Existing test guidelines and OHTs for in vitro methods (e.g. OHT 66-1) may provide additional suggestions for other type of parameters.</p>	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.ParameterAndResult.Parameter

	<p>For guideline methods, all relevant parameters are listed.</p> <p>In case of a non-guideline method, the listed parameters are from existing OECD test guidelines, where the use of the parameters is explained. E.g. CV75 is the test chemical concentration that results in 75% cell viability. The PC value is obtained by interpolation in case a full dose response is not obtained for the test material.</p> <p>Provide in the remarks field, other information that provides explanation of the parameter. E.g. when % depletion is selected, provide information on what is depleted (e.g. cysteine, lysine, etc.).</p> <p>Explanation of some parameters:</p> <p>EC 1.5, 150 and 200 represents the concentration where the test material triggers the effect at the limit (e.g. 1.5, 150 or 200) prescribed by the method used.</p> <p>No-observed effect concentration (NOEC) is defined as the test concentration below the lowest concentration that did result in a significant effect in the specific experiment.</p> <p>Lowest-observed effect concentration (LOEC) is the lowest concentration out of the tested concentrations at which a statistically significant difference from the control group is</p>	
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	<p>observed.</p> <p>PC10, 50, 80 represents the concentration of a test material where the response is 10, 50 or 80% of the response induced by the reference chemical. PC values can be used when incomplete or ambiguous dose response curves are obtained and EC values cannot be calculated..</p> <p>CL, in vitro, INT is in vitro intrinsic (metabolic) clearance.</p>	
Result for the parameter	Provide the result for the selected parameter and select the appropriate unit.	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.ParameterAndResult.ParameterResult
Parameter and result		
Other observations		FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation
Observation	<p>Picklist: Indicate other observations that are important for results interpretation such as information on cytotoxic concentrations, precipitation observed at specific concentrations, other parameters measured. Specify the observation and respective test concentration(s). Alternatively or in addition, use the field 'Any other information on results incl. tables'. If you refer to table(s), use appropriate table numbers (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD Programme,</p>	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation.Observation

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	Pesticides NAFTA or EU REACH) thereof.	
Concentration	Provide the result for other observations and select the appropriate unit.	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation.Concentration
Other observations		FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation
Results for the test material	<p>Picklist: The options in the picklist are derived from existing in vitro OECD test guidelines.</p> <p>Indicate the result of the test conducted.</p> <p>In the remarks field additional information can be added. For example when selecting binder additional information could be 'competitive', 'non competitive', 'specific' or 'non-specific'.</p> <p>Example of results from TG442C, DPRA:</p> <ul style="list-style-type: none"> - Minimal reactivity - Low reactivity - Moderate reactivity - High reactivity 	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.ResultsForTheTestMaterial
Acceptance of results	<p>Picklist: Select the element for which acceptance criteria exist and indicate in the remarks field if the results are valid or invalid.</p> <p>In case results are invalid, please describe in the next field 'Remarks on results' why the result is invalid (e.g. precipitation observed, toxicity of the test material, co-elution with the peptide, etc.), and</p>	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.AcceptanceOfResults

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	what is the impact of invalid data on the results.	
Remarks on results	<p>This field can be used for:</p> <ul style="list-style-type: none"> - explaining expert judgement, in case it was applied; - providing a justification; - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - providing information in case a result may be over-estimated or under-estimated; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; - explaining the impact on the results in case one or more acceptance criteria were not met; - any additional information. 	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.RemarksOnResults
Attached material		FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.AttachedMaterial
Type of attachment	<p>Picklist: Choose the type of document from the picklist or select 'other:'.</p> <p>For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here or in the overall results section.</p> <p>Upload file(s) containing data or</p>	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.AttachedMaterial.AttachmentType

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	results by clicking the 'Select files' button. As appropriate, enter any additional information, e.g. language. The file name and the filename extension is displayed after uploading the document.	
Attachment	Attach the document indicated in the field "Type of attachment".	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.AttachedMaterial.Attachment
Attached material		FLEXIBLE_RECORD.Intermediate Effects.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Test results		
Overall remarks, attachments		FLEXIBLE_RECORD.Intermediate Effects.OverallRemarksAttachments
Overall remarks	<p>In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	FLEXIBLE_RECORD.Intermediate Effects.OverallRemarksAttachments.RemarksOnResults
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).	FLEXIBLE_RECORD.Intermediate Effects.OverallRemarksAttachments.AttachedBackgroundMaterial

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	Copy this block of fields for attaching more than one file.	
Attached document	<p>Provide any additional documents relevant for the submission, not already provided under the methods or results section or in the full study report. Choose the type of document from the picklist or select other.</p> <p>Examples are:</p> <ul style="list-style-type: none"> - Scientific publication - GLP documentation - (Q)SAR: supporting information - Data analysis file (calculation of parameters) - Data supporting the reliability and sensitivity of the method - Specific information on the test material or test system - Justification - Expert judgement - Other <p>For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section.</p> <p>Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g. language. The file name is</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument</p>

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	displayed after uploading the document.	
Remarks	<p>As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.</p> <p>If required, an electronic copy of the full study report or QSAR QPRF reporting forms can be attached as WORD, pdf or other document type.</p>	FLEXIBLE_RECORD.Intermediate Effects.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material		
Attached full study report	If required, an electronic copy of the full study report or QSAR QPRF reporting forms can be attached as WORD, pdf or other document type.	FLEXIBLE_RECORD.Intermediate Effects.OverallRemarksAttachments.AttachedStudyReport
Attached (sanitised) documents for publication	If required, an electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. These attachments should be sanitised if needed.	FLEXIBLE_RECORD.Intermediate Effects.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion		FLEXIBLE_RECORD.Intermediate Effects.ApplicantSSummaryAndConclusion
Interpretation of results / observations		FLEXIBLE_RECORD.Intermediate Effects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations
Overall results and conclusion	<p>Provide the overall result for the test material, on basis of one or more experiments and all observations reported in this template.</p> <p>Convey a clear statement on the mechanistic information obtained.</p> <p>Add the effect concentration in the next fields.</p>	FLEXIBLE_RECORD.Intermediate Effects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.OverallResults

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	<p>Example from h-CLAT: The RFI of CD86 is greater than 150% at 2 tested concentrations (with cell viability \geq 50%) in 2 of 2 experiments. Therefore the test material is activating dendritic cells and is a possible skin sensitizer.</p>	
Type of result	<p>Picklist: Indicate if the results are qualitative when the result is yes/no or positive/negative or quantitative when dose-response information is obtained and an effect level (concentration) can be determined.</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.TypeOfResult</p>
Effect concentration	<p>Picklist: Where available, provide the effect concentration taking into account results from more than one experiment.</p> <p>Explanation of some parameters:</p> <p>EC 1.5, 150 and 200 represents the concentration where the test material triggers the effect at the limit (e.g. 1.5, 150 or 200) prescribed by the method used.</p> <p>No-observed effect concentration (NOEC) is defined as the test concentration below the lowest concentration that did result in a significant effect in the specific experiment.</p> <p>Lowest-observed effect concentration (LOEC) is the lowest concentration out of the tested concentrations at which a statistically significant difference from the control group is observed.</p> <p>PC10, 50, 80 represents the</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.EffectConcentrationChoice</p>

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	<p>concentration of a test material where the response is 10, 50 or 80% of the response induced by the reference chemical. PC values can be used when incomplete or ambiguous dose response curves are obtained and EC values cannot be calculated.</p>	
Concentration	<p>Provide the effect concentration and select the appropriate unit.</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.ApplicantSSummaryAndConclusion.InterpretationOfResult sObservations.Concentration</p>
Remarks	<p>Include any remarks as appropriate.</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.ApplicantSSummaryAndConclusion.InterpretationOfResult sObservations.Remarks</p>
Executive summary		<p>FLEXIBLE_RECORD.Intermediate Effects.ApplicantSSummaryAndConclusion.ExecutiveSummary</p>
	<p>If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective free text template if available from the drop-down list or copy it from the corresponding document.</p> <p>You may also provide information on other existing data or studies that confirm the results obtained.</p> <p>Consult the programme-specific guidance (e.g. EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009; OECD HPVC, Pesticides NAFTA or EU REACH) thereof.</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.ApplicantSSummaryAndConclusion.ExecutiveSummary.ExecutiveSummary</p>

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5.9 Medical data - Endpoint summary

Purpose:

Where available and without prejudice to Article 10 of Council Directive 98/24/EC (1), practical data and information relevant to the recognition of the symptoms of poisoning and on the effectiveness of first aid and therapeutic measures shall be submitted. Such data and information shall include reports of any studies investigating antidote pharmacology or safety pharmacology. Where relevant, the effectiveness of potential antagonists to poisoning shall be investigated and reported.

Data and information relevant to the effects of human exposure, where available, shall be used to confirm the validity of extrapolations made and conclusions reached with respect to target organs, dose-response relationships, and the reversibility of adverse effects. Such data may be generated following accidental, occupational exposure or incidents of intentional self-poisoning, and shall be reported if available.

The document should contain the information needed to be reported according to the list of end points for medical data SANCO/12483/2014– rev. 3 (https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_temp-list-endpoints_rev-3.pdf?)

For microorganisms this document should be used to summarise the available data for 5.1 Basic information including Medical surveillance on manufacturing plant personnel, Sensitisation/allergenicity observations and Direct observation e.g. clinical cases

ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans - v.5.0 (Final) [July 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide brief description of relevant studies and effects e.g. Limited; new active substance,-no detrimental effects on health in manufacturing personnel. For example: - Limited; new active substance, - no detrimental effects on health in manufacturing personnel	Header 1	ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Provide additional information related to the potential effects on	Header 1	ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans.Discussion

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	human health of the micro-organism, including consideration of its pathogenic potential, its ability to infect and its toxicological effects.		
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5.9.1 Medical surveillance on manufacturing plant personnel and monitoring studies

Purpose:

Chemical and Microorganism (Active): Available reports of occupational health surveillance programmes, supported with detailed information on the design of the programme and on exposure to the active must be submitted. Such reports should, where feasible, include data relevant to the mechanism of action of the active and report of adverse health effects, including allergenic responses to chemicals in humans. These reports shall, where available, include data from persons exposed in manufacturing plants or after application of the active (e.g. in efficacy trials).

ENDPOINT_STUDY_RECORD.HealthSurveillanceData - v.7.3 (Final) [September 2020]			
Name	Instructions	Type	Filed Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.Data Source

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Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods
Study type	<p>Select the appropriate study type. Optionally, include details in the supplementary remarks field.</p> <p>Definitions:</p> <ul style="list-style-type: none"> - Biological effect monitoring: involves the measurement of a biological change that is non-adverse and reversible (in contrast to medical monitoring), e.g. liver toxicity biomarkers (i.e. activity of aminotransferase and other enzymes). - Biological exposure monitoring: measurement of biomarkers to assess the exposure from dietary, environmental or occupational sources. Biomarkers of exposure include either the measurement of levels of chemical agents and their metabolites in body fluids, tissue, cells or excreta, or the measurement of biological responses such as cytogenetic and reversible physiological changes in the exposed individuals. - Health record from industry: a review of medical records and occupational exposure. - Health record, other: any other review of medical history and records (e.g. exposed non-occupational). - Medical monitoring: aims to measure early signs and symptoms of adverse effects for preventive reasons. - Medical screening: method for detecting disease or body dysfunction before an individual would normally seek medical care. Aim: early diagnosis and treatment. - Other: any other type of study or information, e.g. self-reported symptoms. 	Open list with remarks	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.StudyType
Endpoint addressed	<p>If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify.</p> <p>NOTE: The list of endpoints provided is a generic</p>	Multi select open list	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.EndpointAddressed

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	list. Some endpoints may not be applicable for the type of study summarised in this record.		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Method		Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method
Type of population	Indicate whether subjects of the general population and/or from an occupational environment were investigated. If 'Other' is selected, please include additional details in the free text box. If two independent studies are reported by the same report, use two separate records.	Multi select open list	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method.TypeOfPopulation
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method.EthicalApproval
Details on study design	Include detailed information on the design of the health surveillance programme and exposure to the substance in question and to other chemicals. Include or attach tables as appropriate.	Text area	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method.DetailsOnStudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.HealthSu

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			veillanceData.ResultsAndDiscussion
Results	Describe the results of the health surveillance study. In addition, include or attach tables and/or an excerpt from the study report.	Text area	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ResultsAndDiscussion.Results
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ApplicantSummaryAndConclusion

5.9.2 Data collected on humans

Purpose:

Where available, reports from studies with humans, such as tests on toxicokinetics and metabolism, or tests on skin irritation or skin sensitisation, shall be submitted. In general, the reference values shall be based on animal studies, but if appropriate scientifically valid and ethically generated human data are available and show that humans are more sensitive and lead to lower regulatory limit values, these data shall take precedence over animal data.

This document can also be used to report Dislodgeable Foliar Residues studies cited in operator exposure assessments.

**ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther - v.7.3 (Final)
[September 2020]**

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods
Type of study / information	Briefly indicate the type of information (which does not fit into any of the specific chapter.)	Multi-line text	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.TypeOfStudyInformation
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.	Multi select open list	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.EndpointAddressed
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.EthicalApproval
Details on study design	Describe the study design including any relevant information from a study report, publication or other source. Include or attach tables or excerpts from study report as appropriate.	Text area	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.DetailsOnStudyDesign
Exposure assessment	Indicate whether the exposure was measured or estimated. For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.ExposureAssessment

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Details on exposure	<p>Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.</p> <p>Explanations:</p> <ul style="list-style-type: none"> - TYPE OF EXPOSURE: Characterise type of exposure including information on manufacturing / processing / use as applicable. If available, describe special exposure situations / workplaces. - TYPE OF EXPOSURE MEASUREMENT: Indicate relevant predefined type(s); delete those being not applicable. - EXPOSURE LEVELS: Give exposure level(s) reported (with units) or insert/attach table, for several exposure conditions and levels. - EXPOSURE PERIOD: Describe when subjects were exposed and duration of exposure, i.e., hours, hours per day, days, days per week, weeks, months, years, person years, other. - POSTEXPOSURE PERIOD: State period of time elapsed between last exposure/first examination or time study was conducted. - DESCRIPTION / DELINEATION OF EXPOSURE GROUPS / CATEGORIES: If several exposure groups (e.g. different concentrations or durations) are analysed, identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc. 	Text template	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.DetailsOnExposure
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion
Results	Provide exposure data as available and describe any relevant outcome of the study. If appropriate present the data in tabular form and/or attach excerpt(s) from the study report.	Text area	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion.Results
Any other information on	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDi

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results incl. tables			scussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ApplicantSummaryAndConclusion

5.9.3 Direct observation – Endpoint study record

Purpose:

Chemical: Available reports from the open literature, relating to clinical cases and poisoning incidents, shall be submitted.

Microorganism (Active): Available reports from the open literature on the microorganism or closely related members of the taxonomic group (relating to clinical cases) shall be submitted.

Such reports shall, where available, contain complete descriptions of the nature, level and duration of exposure, as well as the clinical symptoms observed, first aid and therapeutic measures applied and measurements and observations made, as well as follow up studies undertaken.

ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases - v.7.3 (Final) [September 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block For micro-organisms, direct observations and clinical cases should be considered as supporting information.	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods
Study type	Select type of medical data.	Open list with remarks	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.StudyType
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.	Multi select open list	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.EndpointAddressed
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.TestMaterials.TestMa

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			terialInformati on
Method		Header 2	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Metho d
Type of population	Indicate whether subjects of the general population and/or from an occupational environment were investigated. If 'Other' is selected, please include additional details in the free text box. If two independent studies are reported by the same report, use two separate records.	Multi select open list	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Metho d.TypeOfPopul ation
Subjects	Describe the subject(s) examined based on the freetext template (delete/add elements as appropriate). As an option you may include an excerpt from the study report.	Text template	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Metho d.Subjects
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate in the supplementary remarks field.	Open list with remarks	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Metho d.EthicalAppro val
Route of exposure	Indicate the route of exposure. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Metho d.RouteOfExpo sure
Reason of exposure	Indicate the reason of exposure e.g. intentional or occupational unitentional.	Open list	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Metho

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			d.ReasonOfExposure
Exposure assessment	Indicate whether the exposure was measured or estimated.	Closed list with remarks	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.ExposureAssessment
Details on exposure	Describe type and incidence of exposure including quantitative data if available, i.e. state if single or multiple exposure, duration, exposure concentrations (if inhalation), amount of chemical or micro-organisms ingested, dermal contact etc. Include methods of analysis if data available. If exposure was estimated, describe how this was done, if available.	Text area	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.DetailsOnExposure
Examinations	Indicate type of examinations performed and at what time after start of exposure. Use freetext template (delete/add elements as appropriate). As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.Examinations
Medical treatment	Indicate if and what medical treatment exposed / intoxicated persons received.	Text area	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.MedicalTreatment
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.DirectObservati

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			onsClinicalCases.ResultsAndDiscussion
Clinical signs	Describe any relevant signs and symptoms observed.	Text area	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.ClinicalSigns
Results of examinations	Describe the results of examinations based on freetext template (delete/add elements as appropriate). As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.RsExaminations
Effectivity of medical treatment	Indicate whether and during what time intoxicated persons responded to medical treatment.	Text area	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.EffectivityMedicalTreatment
Outcome of incidence	Describe the clinical manifestation of signs and symptoms, partial or total recovery after what time etc. If reported, give data on any follow-up examinations.	Text area	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.Outcome
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCase

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			s.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ApplicantSummaryAndConclusion

5.9.4 Epidemiological studies – Endpoint study record

Purpose:			
Provide data of relevant epidemiological studies, if available.			
ENDPOINT_STUDY_RECORD.EpidemiologicalData - v.7.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods
Study type	Select appropriate study type.	Open list with remarks	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.StudyType
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list.	Multi select open list	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.EndpointAddressed

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	Some endpoints may not be applicable for the type of study summarised in this record.		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method
Type of population	Indicate whether subjects of the general population and/or from an occupational environment were investigated. If two independent studies are reported by the same report, use two separate records.	Multi select open list	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.TypeOfPopulation
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.EthicalApproval
Details on study design	Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Explanations: - HYPOTHESIS TESTED: If study type is cohort or case control study, state the hypothesis(es) tested in this study. - STUDY PERIOD: Give dates during which the data were collected (from ... to ...) - SETTING: Indicate the setting where this study took place, e.g., occupational, residential, hospital-based, clinical practice, environmental (e.g., fenceline of waste sites, air monitoring); its geographic location(s); and any other pertinent information. - STUDY POPULATION: Include details on the study population using the predefined items and inserting additional ones if required. Alternatively include or attach a table and refer to respective Table no. - COMPARISON POPULATION: Indicate one of the predefined types; delete those being not applicable. Provide details, e.g., note the parameters that were	Text template	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.DetailsOnStudyDesign

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	'matched' (i.e., smoking, age, sex, etc.). - HEALTH EFFECTS STUDIED: Describe as appropriate. Note whether the diagnosis of the effects was made blind to exposure status. Alternatively include or attach a table and refer to respective Table no.		
Exposure assessment	Indicate whether the exposure was measured or estimated. For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.ExposureAssessment
Details on exposure	Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Explanations: - TYPE OF EXPOSURE: Characterise type of exposure including information on manufacturing / processing / use as applicable. If available, describe special exposure situations / workplaces. - TYPE OF EXPOSURE MEASUREMENT: Indicate relevant predefined type(s); delete those being not applicable. - EXPOSURE LEVELS: Give exposure level(s) reported (with units) or insert/attach table, for several exposure conditions and levels. - EXPOSURE PERIOD: Describe when subjects were exposed and duration of exposure, i.e., hours, hours per day, days, days per week, weeks, months, years, person years, other. - POSTEXPOSURE PERIOD: State period of time elapsed between last exposure/first examination or time study was conducted. - DESCRIPTION / DELINEATION OF EXPOSURE GROUPS / CATEGORIES: If several exposure groups (e.g. different concentrations or durations) are analysed, identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc.	Text template	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.DetailsOnExposure
Statistical methods	Describe all statistical methods used and the data to which they were applied (include sample size and power calculations, if available).	Multi-line text	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.StatisticalMethods
Any other information on	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsA

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materials and methods incl. tables			ndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion
Results	Provide exposure data as available. Give numbers of cases for each effect/disease/parameter under consideration, include measures of disease frequency (SMRs, ORs, PMRs, RR, prevalence, incidence, adjusted and/or crude rates), correlations, distributions etc., statistical data (significance, confidence intervals). If appropriate present the data in tabular form. Upload predefined table in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').	Text template	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.Results
Confounding factors	Indicate any (possible) confounding factor(s), e.g. multi chemical exposure or smoking, and discuss their influence on the observed causal association.	Text area	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.ConfoundingFactors
Strengths and weaknesses	Explain findings and discuss any other factors, i.e. bias, validity issues, reliability issues (including the adequacy of the exposure estimation or measurements), representativeness concerns, unique nature of study, influence of past exposures, latency, turnover rates in occupation studies.	Text area	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.StrengthsWeaknesses
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.OverallRemarksAttachments
Applicants summary and	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ApplicantSummaryAndConclusion

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conclusion			
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6. Residues in or on treated products, food and feed - Endpoint summary

Purpose:

Provide an overall conclusion on the residues information submitted in Section 6 and to address any points where a suitable sub-section could not be identified. This summary can also be useful to provide summary and rationale for specific cases (e.g. substances that are Annex IV candidate).

ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs v.5.0 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary.DataProtection
Description of key information	<p>Please report here an overall narrative summary of the residue section. Indicate whether all data requirements were fulfilled in all sub-sections of Section 6. Should it not be the case, please indicate the main deviations/missing data/substantive arguments that support the overall conclusions of the residue section.</p> <p>For MRL applications, this rich text field should be used by the applicant to report, in accordance</p>	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.KeyInformation

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	<p>with article 7 1b of Regulation 396/2005, a presentation of the application dossier including: (i) a summary of the application; (ii) the main substantive arguments.</p> <p>In this rich text field, you may also address any points where a suitable sub-section could not be identified. For example, this can be useful for specific purposes for MRL application (e.g. include an active substance in IV”) or for any other specific cases for which the standard endpoint summaries may not be fully suitable. However, there is no need to repeat tables and summaries that are duly reported in the respective endpoint summaries of the detailed sections. For example, residue trials data selected to derive and propose a MRL shall be reported in Section 6.3.</p>		
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFee dingstuffs.Discussion
Attached background material			ENDPOINT_SUMMARY.ResiduesInFoodAndFee dingstuffs.Discussion.At tachedBackgroundMate rial
Attached document	The original file only needs to be attached	Single file attachment	ENDPOINT_SUMMARY.ResiduesInFoodAndFee

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	here if it differs from the file in Attached (sanitised) documents for publication.		dingstuffs.Discussion.At tachedBackgroundMate rial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY. ResiduesInFoodAndFee dingstuffs.Discussion.At tachedBackgroundMate rial.Remarks
Attached background material	You can attach here any useful document that support the above statement. However, do not repeat the attachments that are already reported in the respective endpoint summaries of the detailed sections. For example, the MRL OECD calculator.xls shall be reported in Sections 6.3 and 6.7.2, but <u>not</u> here.		
Attached (sanitised) documents for publication	Same as above with sanitized version for the document(s).	Attachments list	ENDPOINT_SUMMARY. ResiduesInFoodAndFee dingstuffs.Discussion.At tachedSanitisedDocsFor Publication

6.1 Storage stability of residues – Endpoint summary

Purpose:

Provide a summary overview of the demonstrated freezer storage stability period per compound per matrix and to conclude whether the storage stability of residues in matrices of plant and animal origin was sufficiently elucidated in the context of the present application.

ENDPOINT_SUMMARY.StabilityResiduesCommodities v.1.3 (Final)

Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY. StabilityResiduesComm odities.AdministrativeD ataSummary

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		Confidentiality	ENDPOINT_SUMMARY.StabilityResiduesComm odities.AdministrativeD ataSummary.DataProte ction
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.StabilityResiduesComm odities.LinkToRelevantS tudyRecord
Study name / type	Provide here the link to the most relevant study (or studies) from which the key value(s) for the storage stability of residues is/are derived.	Endpoint reference list	ENDPOINT_SUMMARY.StabilityResiduesComm odities.LinkToRelevantS tudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.StabilityResiduesComm odities.LinkToRelevantS tudyRecord.Results
Description of key information	Please make a statement as to whether the storage stability of residues in matrices of plant and animal origin was sufficiently elucidated in the context of the present application (according to the relevant data requirements and OECD test guidelines 506) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Respective detailed parameters on the available key studies used for risk assessment should be reported in the detailed blocks below (one repeatable block for "storage stability - plant" and one	Header 1	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation

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	repeatable block for "storage stability - animal").		
		Rich text area	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation.KeyInformation
Storage stability - plant	Repeat this block to create one row per key result (e.g. one row for each combination stability matrix/compound(s) covered with the most critical storage stability conditions.		ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant
Category	Select the matrix to which the key results apply (e.g. commodities with "high water content"). Category defined according to OECD TG 506.	Open list with remarks	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.Category
Commodity	Indicate the commodity(ies) tested in the study (multi-selection is possible).	Multi select open list with remarks	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.Commodity
Compound(s) covered	Indicate which compound(s) were tested for storage stability. If parent and metabolites were tested independently, report it in different rows. If the sum of parent and metabolites was tested for stability, specify it in this field.	Text	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.CompoundSCovered
Substance(s)	Link (cross reference) to the substance(s) indicated in the above field.	Entity reference list	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.SubstanceS

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Temperature (°C)	Indicate the temperature tested in the study (e.g. -18°C).	Decimal	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.StorageStabilityPlant.Te mperature
Tested period (length of the study)	Enter the entire period (as number) for which stability of the compounds was tested. The preferred reporting unit is months (m). Enter data using one decimal point, e.g. 244 days would be 3.8 months using an average of 30.4 days per month. If the period is lower than one month, report in full days. Example: If the study investigated storage stability for 24 months but residues are only stable for 12 months, please report 24 months in the present field.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.StorageStabilityPlant.Te stedPeriod
Demonstrated stability period	Enter the period (as number) for which stability of the compounds was demonstrated. The preferred reporting format for storage stability is months (m). Enter data using one decimal point, e.g. 244days would be 3.8 months using an average of 30.4 days per month. If stability is lower than one month, report in full days.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.StorageStabilityPlant.De monstratedStability
Remarks	Add here any relevant information on the preparation of the	Multi-line text	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.

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	<p>samples and/or on any specific storage conditions for which stability has been shown.</p> <p>Examples for additional comments:</p> <ul style="list-style-type: none"> - Mode of fortification, e.g. whole commodity or homogenised; - Analysis of fortified samples or samples from metabolism studies with incurred residues; <p>For specific cases, e.g. stability of sum of compounds sharing common moiety, use the same field to explain.</p>		StorageStabilityPlant.Re marks
Storage stability - plant			
Storage stability - animal	<p>Repeat this block to create one row per key result (e.g. one row for each combination animal commodity(ies)/compound(s) covered with the most critical storage stability conditions. Fields and instruction are the same as for storage stability in plant matrices.</p>		ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation. StorageStabilityAnimal
Category		Open list with remarks	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation. StorageStabilityAnimal. Category
Commodity	Commodity(ies) covered by the stability study(ies).	Multi select open list with remarks	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation. StorageStabilityAnimal. Commodity

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Compound(s) covered	Indicate which compound(s) were tested for storage stability. If parent and metabolites were tested independently, report it in different rows. If the sum of parent and metabolites was tested for stability, specify it in this field.	Text	ENDPOINT_SUMMARY. StabilityResiduesComm odities.KeyInformation. StorageStabilityAnimal. CompoundSCovered
Substance(s)		Entity reference list	ENDPOINT_SUMMARY. StabilityResiduesComm odities.KeyInformation. StorageStabilityAnimal. SubstanceS
Temperature (°C)		Decimal	ENDPOINT_SUMMARY. StabilityResiduesComm odities.KeyInformation. StorageStabilityAnimal. Temperature
Tested period (length of the study)		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. StabilityResiduesComm odities.KeyInformation. StorageStabilityAnimal. TestedPeriod
Demonstrated stability period	<p>Enter the period (as number) for which stability of the compounds was demonstrated. The preferred reporting format for storage stability is months (m). Enter data using one decimal point, e.g. 244 days would be 3.8 months using an average of 30.4 days per month.</p> <p>If stability is lower than one month, report in full days.</p>	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. StabilityResiduesComm odities.KeyInformation. StorageStabilityAnimal. DemonstratedStability
Remarks	Please report the same text as for stability in	Multi-line text	ENDPOINT_SUMMARY. StabilityResiduesComm

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	plant for the similar field.		odities.KeyInformation.StorageStabilityAnimal.Remarks
Storage stability - animal			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion
	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.Discussion
Attached background material			ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).		
Attached (sanitised) documents for publication	Add any additional document that supports the above key results (e.g. calculation tables, graphs).	Attachments list	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.AttachedSanitisedDocsForPublication

6.1 Storage stability of residues – Endpoint study record

Purpose:

The aim of these studies is to demonstrate the time period for which stability has been shown in representative commodities from crops, by extrapolation to processed fractions derived from crops, and products of animal origin.

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ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod v.4.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.DataProtection
Endpoint	Select from picklist the relevant endpoint (here 'stability of residues in stored commodities').	Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.UsedForMSDS

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Study period		Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.Attach

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			edJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource
Reference	Literature reference v.5.1 (Final)	Literature reference list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResidu

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			esInStoredCommod.Ma terialsAndMethods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Prod uctType
Test guideline			ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Guid eline
Qualifier		Closed list	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Guid eline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Guid eline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Guid eline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Guid eline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Meth odNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma

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			terialsAndMethods.GLP ComplianceStatement
Test material		Header 2	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Test Materials
Test material information		Entity reference field	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Test Materials.TestMaterialIn formation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Test Materials.SpecificDetails OnTestMaterialUsedFor TheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Test Materials.SpecificDetails OnTestMaterialUsedFor TheStudyConfidential
Radiolabelling	Indicate if labelled or non-labelled test material was used. Generally, stability studies are carried out with non-labelled test material. In this case, please indicate "No" in this field. In the rare cases where the commodities used for stability study were obtained from metabolism studies using radiolabelled material, please indicate "Yes" in this field.	Open list with remarks	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Ma terialsAndMethods.Test Materials.Radiolabelling

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Study design		Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommodMaterialsAndMethods.StudyDesign
Bulk raw agricultural commodity (RAC)	<p>Raw agriculture commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing, or for processing into food for sale to the consumer. It includes irradiated primary food commodities and products after removal of certain parts of the plant or parts of animal tissue. The term RAC means the same as "primary food commodity" or "primary feed commodity".</p> <p>Indicate here the raw agricultural commodity name or the nearest name equivalent to the commodity description being used in the study. If not available, select 'other:' and specify commodity(ies) on which storage stability test was performed.</p> <p>Please note that the codes and names of raw agricultural commodities currently contained in the picklist are extracted from the Codex Classification of Foods and Animal Feeds, issued by the</p>	Multi select open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommodMaterialsAndMethods.StudyDesign.Commodity

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	<p>Joint FAO/WHO Food Standards Programme. This will be improved in the next IUCLID release to match the classification used in the EU PPP Regulation. Meanwhile, please select the nearest name equivalent to the commodity description being used in the study.</p>		
Details on stored commodities	<p>Provide detailed description of commodities / matrices stored (whether raw or processed).</p>	Text area	<p>ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommodMaterialsAndMethods.StudyDesign.DetailsOnStore dCommodities</p>
Storage conditions	<p>Specify the main storage conditions such as freezer type (e.g. deep-frozen room), freezer temperature (e.g. -18°C), length of storage (e.g. 24 months), commodity form (e.g. extract, macerate, homogenized) and detailed conditions (e.g. dark or potential control condition including any special storage conditions, e.g. stabilizer added, humidity control, acid or base, lighting, container types/size, sample sizes/weight(s), etc.</p> <p>Use "insert existing templates" and delete/add elements as appropriate.</p>	Text template	<p>ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommodMaterialsAndMethods.StudyDesign.StorageCondi tions</p>

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Sampling and analytical methodology		Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommodMaterialsAndMethods.SamplingAndAnalyticalMethodology
Details on sample collection	Include details on sampling time (age of raw commodity in days at each sampling time), number of samples/replicates. Use "insert existing templates" and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommodMaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleCollection
Details on sample handling and preparation	<p>Studies may be either performed on samples from treated crops or animals with incurred residues or by fortification experiments. In the latter case, aliquots of prepared control samples shall be spiked with a known amount of chemical before storage under normal storage conditions.</p> <p>Include details on the sample handling and preparation. The following information should be addressed: Handling and shipping of commodities, any preparation done prior to extraction (e.g. homogenised samples). It should be clear whether samples contain incurred residues or if samples were spiked/fortified with the active</p>	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommodMaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndPreparation

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	<p>substance/metabolites; whether samples were homogenised or not.</p> <p>Use “insert existing templates” and delete/add elements as appropriate.</p> <p>E.g. <i>RAC</i> samples were homogenized and fortified with <i>test material</i> at about <i>X</i> mg/kg.</p>		
Details on analytical methodology	<p>Provide details on the analytical method, i.e. describe methods fully or reference them if previously submitted. It may be sensible to outline the analytical methodology in Section 'Analytical methods'. If the method is already reported in the Section 'Analytical methods', reference to the corresponding endpoint study record (UUID) is sufficient.</p>	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod. MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p>	Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod. MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
	<p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create</p>	Rich text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod. MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation

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	formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.		
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion
Residue levels	<p><u>Option 1:</u> Possibility to use the repeatable block to specify the residue level of each analyte determined for a given commodity at each sample date. Copy this block of fields for recording the results of multiple samplings.</p> <p><u>Option 2:</u> If more convenient, you may skip this block and directly report the detailed results in the field below "Any other information on the results including tables". In such a case, simply copy/paste free text and Table(s), according to the recommended templates for this type of study.</p>		ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels
Test commodity		Open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.TestCommodity

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Other details on test commodity		Multi-line text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.OtherDetailsOnTestCommodity
Date of sample		Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.DateOfSample
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalysisSampleID
Analysis sample description		Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalysisSampleDescription
Analyte measured			ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.Resid

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			ueLevels.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MethodID
Residue level		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ResidueLevel
Mean residue level		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MeanResidueLevel
Residue level (% of nominal spiking level)		Range (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ResidueLevelOfNominalSpikingLevel
Mean residue level (% of nominal spiking level)		Decimal	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MeanResidueLevelOfNominalSpikingLevel
Procedural recovery control (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ProceduralRecoveryControl
Mean procedural recovery control (%)		Decimal	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasur

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			ed.MeanProceduralRecoveryControl
Analyte measured			
Residue levels			
Storage stability of residues (Sample Integrity)	<p>Briefly describe the conditions, which residues of [parent and/or metabolites] appeared to be [stable or [decreased or increased] by [percentage]].</p> <p><u>Example:</u> The residue of [parent and/or metabolites] decreased slowly with time. After [x months] of storage it amounted to [XX]% of the initial value and after [y months] of storage it amounted to [YY]% of the initial value</p> <p>Please make one statement per commodity.</p> <p>(Optional) Provide graph of residue stability in matrix as applicable as percent recovery over time, in an attachment (in the block below).</p>	Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.StorageStability
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on the results. You can also open a rich text editor and create	Rich text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.AnyOtherInformationOnResul

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	<p>formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.</p> <p>If you did not use the option 1 to report the detailed results for each analyte determined for a given commodity at each sample date, please report the detailed results here, in one or several table(s).</p> <p>Please use the recommended formats available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.1]. Repeat the tables as much as necessary.</p> <p>NB: According to OECD 506 guidance correction for day zero recovery and/or procedural recovery is not recommended.</p> <p>Other formats can be used provided that all information requested in OECD TG 506 is reported and that they are readable by the system.</p>		tsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.Ov

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			erallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ApplicantSummaryAndConclusion.Conclusions
Executive summary	<p>Briefly summarise the relevant aspects of the study(ies) including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document.</p> <p><u>Example:</u></p> <p>Samples of [ground or whole crop/matrix] were fortified with [analytes] at a level of [fortification level] and put into storage at [temperature]. At intervals of [xx, yy, and zz] months, stored samples and freshly fortified samples were analyzed for residues of [list analytes].</p> <p>At each storage interval, [analytes] were determined using Method [Method ID], a [describe method]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of</p>	Rich text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ApplicantSummaryAndConclusion.ExecutiveSummary

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	<p>[xx] mg/kg (ppm), thus validating the method. The limit of quantitation (LOQ) was [xx] ppm per analyte for [matrices].</p> <p>Under these conditions, residues of [active ingredient and metabolites (if applicable)] were stable {or [decreased or increased] by [percentage]} in [crop/matrix] for [duration of time].</p>		
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6.2 Metabolism, distribution and expression of residues

6.2.1 Metabolism of residues in plants and in rotational crops – Endpoint summary

Purpose:

provide a summary of the key metabolism studies on residues in primary and rotational crops and used to conclude whether the nature of residues in plant (primary and rotational crops) was sufficiently elucidated. Please briefly summarize the parameters of the key metabolism studies.

ENDPOINT_SUMMARY.MetabolismPlants v.1.1 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MetabolismPlants.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MetabolismPlants.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation
	Please make a statement whether the nature of residues in plant (primary and rotational crops) was sufficiently elucidated in the context of the present application and highlight data gap(s) and the non-standard uncertainty(ies) (according to the relevant data requirements OECD TG 501 and OECD TG 502), if any. For rotational crop studies, please make a statement here whether the study parameters cover the maximum soil concentration expected for the active substance (and its soil	Rich text area	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.KeyInformation

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	metabolites), considering the use and use pattern under assessment. Respective detailed parameters on the available key studies used for risk assessment should be reported in the repeatable block below.		
Primary crops	Repeat this block to create one row per key metabolism study. This table should mimic the current list of endpoints summary table. There is no need to report the detailed results of the studies but please be accurate on the study key parameters.		ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops
Link to relevant studies	Provide here the link to the relevant study(ies) corresponding to the created row.	Endpoint reference list	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops .RelevantStudies
Crop groups	Picklist (based representative crop groups defined in Annex 1 of OECD TG 501): Indicate the metabolism crop group covered by the study(ies) reported in this row (e.g. root crops). If the group is not in the picklist, please use "other" specify the group in the opening cells.	Closed list	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops .CropGroups
Commodity	Indicate the commodity(ies) for which nature of residues was investigated in the	Multi select open list with remarks	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops .Commodity

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	study. Multi-selection is possible (E.g. wheat grain + wheat straw).		
Treatment type	Indicate the type of treatment (e.g. foliar) tested in the study. If different types of treatments were tested in the same study, please create a separate row for each of the treatment type.	Multi select open list with remarks	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops .TreatmentType
Application rate	Indicate the application rate (with the unit) tested in the study (e.g. 1 kg a.s./ha). If different application rates were tested in the same study, there is the possibility to report both in the same cells (e.g. 1 kg a.s./ha; 2 kg a.s./ha) or to create separate rows as more appropriate.	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops .ApplicationRate
DAT	DAT (days after treatment): Indicate the time (in days) between treatment and sampling. Possibility to report a series of figures (e.g. 1; 3; 7; 14) and to specify the sampled commodities (e.g. 1 (fruit); 3 (leaves)...).	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops .Dat
Primary crops			
Rotational crops	Repeat this block to create one row per key metabolism study. This table should mimic the current list of endpoints summary table. There is no need to report the detailed results of the studies		ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops

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	but please be accurate on the study key parameters.		
Link to relevant studies	Provide here the link to the relevant study(ies) corresponding to the created row.	Endpoint reference list	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.RelevantStudies
Crop groups	Picklist (based on representative crop groups defined in OECD TG 502): Indicate the metabolism crop group covered by the study(ies) reported in this row (e.g. root/tuber crops). If the group is not in the picklist, please use "other" specify the group in the opening cells.	Open list	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.CropGroups
Commodity	Indicate the commodity(ies) for which nature of residues was investigated in the study. Multi-selection is possible (E.g. wheat grain + wheat straw).	Multi select open list with remarks	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.Commodity
PBI	PBI (Plant back interval): Indicate the time (in days) between treatment (application of active substance on previous crops or on bare soil) and planting. There is the possibility to report a series of figures (e.g. 30, 120 or 365 days).	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.Pbi
Application rate	Indicate the application rate (with the unit) tested in the study (e.g. 1 kg a.s./ha). If different application rates were tested in the	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.ApplicationRate

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	same study, there is the possibility to report both in the same cells (e.g. 1 kg a.s./ha; 2 kg a.s./ha) or to create separate rows as more appropriate.		
Remarks	Indicate if the application was made on "bare soil" or on "growing crops". If application is done on growing crops, please specify the growth stage at application (BBCH scale) to be able to calculate the foliar interception accordingly.	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.Remarks
Rotational crops			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. MetabolismPlants.Discussion
	This section can be used to add any additional useful text. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY. MetabolismPlants.Discussion.Discussion
Attached background material			ENDPOINT_SUMMARY. MetabolismPlants.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY. MetabolismPlants.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY. MetabolismPlants.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	Add any additional document that supports		

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	the above key information (e.g. calculation tables, graphs). The depicted metabolic pathways can be uploaded here.		
Attached (sanitised) documents for publication	<p>Add any additional document that support the above key results (e.g. calculation tables, graphs) after sanitisation.</p> <p>The overview of metabolism studies [cf. residue Template 6.2 (http://doi.org/10.5281/zenodo.4621089)] can be uploaded here by the applicant, although not mandatory. The uploaded file should not contain confidential material. Please note that the overview of the metabolism studies (excel file) will be generated later by the EMS/RMS during the risk assessment phase, provided that all MSS-composer xml-files of the metabolism studies are available to the RMS/EMS.</p>	Attachments list	ENDPOINT_SUMMARY. MetabolismPlants.Discussion.AttachedSanitised DocsForPublication

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6.2.1 Metabolism of residues in plants and in rotational crops – Endpoint study record

Purpose:

The results of the studies of metabolism in crops are used to elucidate the degradation pathway of the active substance and require the identification of the metabolism and/or degradation products when a pesticide is applied to a crop directly or indirectly.

Studies of metabolism in crops fulfil several major purposes:

- 1) Provide an estimate of the total residues in the various commodities after crop treatment, which allows determination of the distribution of residues within the crop, e.g., whether the pesticide is absorbed through roots or foliage or whether translocation occurs;
- 2) Identify the components of the terminal residue in the various commodities, thus indicating the components to be analysed for in residue quantification studies (i.e., the residue definition(s) for both risk assessment and enforcement).
- 3) Elucidate the metabolic pathway of the active ingredient in treated crops.

Currently, the general recommendation is to use a separate tool ("MSS composer") to report metabolism studies. Therefore, detailed parameters concerning the materials and methods and the results of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out all the fields in the present document.

However, the fields marked as "mandatory" in this document shall be fulfilled in IUCLID to ensure a minimum structured data and to make best use of the report generator.

The XML-files created with the MSS-composer should be uploaded in IUCLID as defined in this chapter and as defined in the general workflow for metabolism studies (see support material).

ENDPOINT_STUDY_RECORD.MetabolismInCrops v. 6.6 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist (for metabolism studies in primary crops, please use the option "metabolism of residues in crops")	Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.Endpoint
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.DataSource

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Materials and methods	<p>Material and methods – common block</p> <p>MATERIALS AND METHODS</p> <p>This part of the metabolism study should mainly be reported in a separate tool which is the “MSS composer”. Therefore, all detailed parameters concerning the materials and methods of the metabolism studies should be contained in the XML-file created with the “MSS-composer” and there is no need to fill out all the fields in the present section. However, the fields marked as “mandatory” shall be fulfilled to ensure a minimum structured data and to make best use of the report generator.</p>	Header 1	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods
Background information		Rich text area	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Ba ckgroundInformation
Product type	<p>The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.</p>	Open list with remarks	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Pr oductType
Test guideline	<p>Mandatory field.</p> <p>Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.</p> <p>Add one block of fields for each guideline when more than one guideline is followed (e.g. US EPA in addition to OECD guideline).</p>		ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Gu ideline
Qualifier	<p>Mandatory field.</p> <p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - 'according to guideline' (if a given test guideline was followed); - 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline'); 	Closed list	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Gu ideline.Qualifier

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	<p>- 'no guideline available' (if so, fill in field 'Principles of method if other than guideline').</p> <p>- 'no guideline required' (if so, fill in field 'Principles of method if other than guideline').</p>		
Guideline	<p>Mandatory field.</p> <p>Select the applicable test guideline, e.g. 'OECD TG 501' (for primary crops) or 'OECD TG 502' (for rotational crops). If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'. If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'.</p> <p>The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields. Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'.</p>	Open list	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Gu ideline.Guideline
Version / remarks	<p>Mandatory field.</p> <p>In this text field, you can enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline); - To indicate if the study was performed prior to the adoption of the test guideline specified; - To indicate if the methodology used was based on an extension of the test guideline specified; - To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. 	Multiline text	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Gu ideline.VersionRemarks
Deviations	<p>Mandatory field.</p> <p>In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary</p>	Closed list with	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Gu ideline.Deviation

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	remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS.	rem arks	
Test guideline			
Principles of method if other than guideline	<p>Mandatory field.</p> <p>If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined free text template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.</p> <p>For a non-guideline experimental study, a high-level free text template can be used for summarising the principle of test, test conditions and parameters analysed / observed.</p> <p>If the free text template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate.</p> <p>Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate.</p>	Text tem plat e	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Me thodNoGuideline
GLP compliance	<p>Mandatory field.</p> <p>Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes' is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed.</p>	Clos ed list with rem arks	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.GL PComplianceStatement
Test material	<p>Test Material – common block</p> <p>This part of the metabolism study should be reported via the "MSS composer". However, test material information and specific details on test material used for the study shall be entered here to link the present study record to the test materials created in this dataset.</p>	Hea der 2	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Te stMaterials

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Test material information	Mandatory field.	Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study	Mandatory field.	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)	Mandatory field.	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Radiolabeling	Mandatory field. Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.Radiolabeling
Radiolabelled test material	Mandatory field. Please indicate the radiolabel of test material. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record)		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial
Radiolabel no.	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.RadiolabelNo
SMILES notation	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SMILESNotation
Radiochemical purity (%)	Mandatory field.	Range (Dec	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Te

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	To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	imal)	stMaterials.Radiolabelled TestMaterial.RadiochemicalPurity
Specific activity as received	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.Radiolabelled TestMaterial.SpecificActivityAsReceived
Specific activity of dose	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.Radiolabelled TestMaterial.SpecificActivityOfDose
Remarks	Field not mandatory. Use this field to enter any remarks.	Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.Radiolabelled TestMaterial.Remarks
Radiolabelled test material			
Crop information		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation
Test crops	The field test crops is not mandatory. Therefore, there is no need to show the subfields 'test crops no, type of rotational crops, crops, crop code, crop variety, scientific name, crop group, growth stage at app, growth stage at harvest, harvested commodities, harvested procedure.		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops
Other details on test crops	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.DetailsOnTestCrops

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Test site and soil properties		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties
Test site type	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.TestSiteType
Soil properties	This field is not mandatory. Therefore, there is no need to show all the subfields below (soil type no, soil type, ph, etc...) which are also not mandatory.		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties
Other details on test site	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.DetailsOnTestSite
Environmental conditions	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions
Application	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record)..	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application
Use pattern information	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		
Sampling and analysis of crop plants	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis
Flowchart of extraction and fractionation	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes

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on schemes			
Sampling and analysis of soil	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysisOfSoil
Appendix: Treatment groups	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Field not mandatory. In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion	This part of the metabolism study should mainly be reported in a separate tool which is the "MSS composer". Therefore, all detailed results of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out the fields of the present section. However, the fields marked as "mandatory" shall be fulfilled to ensure a minimum structured data and to make best use of the report generator.	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion
Total radioactive residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues

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Extraction efficiency of radioactive residues using enforcement method	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod
Quantitation	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.Quantitation
TRR results	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults
Other details on total radioactive residues (TRRs)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues
Extraction, characterisation, and distribution of residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record)	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues
Distribution of parent and metabolites	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites
Other details on distribution of residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfResidues

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Storage stability of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues
Summary of storage conditions	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions
Storage stability of residues (Sample Integrity)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.StorageStability
Summary of radioactive residues in crops	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops
Other details on characterization and identification of residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfResidues
Summary of radioactive residues in soil	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil
Proposed metabolic pathway		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway
Identification of compounds from metabolism study	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway.IdentificationOfCompoundsFromMetabolismStudy

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Metabolic pathway	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway.MetabolicPathway
Metabolic map (picture/graph)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Image	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway.MetabolicMapPictureGraph
Appendix: Metabolites and their parents in treatment groups	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups
Any other information on results incl. tables	Field not mandatory. In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments
Overall remarks	Field not mandatory. In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. If you entered in the study in the MSS composer and/or if the XML-file created with the MSS-composer is available to you, please generate a word report from the MSS-composer (using the adequate feature in the MSS-composer software) and copy/paste this report in this field. Additional text can be added to	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.RemarksOnResults

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	complement the basic report generated by the MSS-composer.		
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document	Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document.	Single file attachment	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication		Attachments list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ApplicantSummaryAndConclusion
Conclusions	Mandatory field. Write here the Applicant's conclusion of the metabolism study in context of the application.	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ApplicantSummaryAndConclusion.Conclusions

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Executive summary	Mandatory field. Briefly summarise the relevant aspects of the study including the conclusions reached in the context of the application.	Rich text area	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. ApplicantSummaryAndC onclusion.ExecutiveSum mary
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Links to support material:

Please find specific instructions on who to structure the results of metabolism studies plants and livestock under the following link:

<https://www.efsa.europa.eu/en/applications/pesticides/tools>

From the page, users will find all instructions to download the MSS composer (part of the Metapath software package), link to the technical manual for the MSS-composer, detailed information on the data flow for metabolism studies and access to the databases of metapath files.

Specific instructions on the process workflow for metabolism data are available in the following document: <https://zenodo.org/record/4785179#.YMjEe6gzbD4>

6.2.2 Metabolism of residues in livestock (incl. fish) – Endpoint summary

Purpose:

provide a summary of the key parameters of metabolism studies on livestock for individual groups of animals used to conclude whether the nature of residues in livestock/fish was sufficiently elucidated. Please briefly summarize the parameters of the key metabolism studies.

ENDPOINT_SUMMARY.MetabolismInLivestock v.3.0 (Final)

Name	Instructions	IUCLID6 DataType	IUCLID6 Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY. MetabolismInLivestock. AdministrativeDataSum mary
		Confidentiality	ENDPOINT_SUMMARY. MetabolismInLivestock. AdministrativeDataSum mary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY. MetabolismInLivestock. LinkToRelevantStudyRe cord
Study name / type	Provide here the link to the most relevant study(ies) from which the key values for magnitude of residues in commodities of	Endpoint reference list	ENDPOINT_SUMMARY. MetabolismInLivestock. LinkToRelevantStudyRe cord.Link

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	animal origin are derived.		
Results		Read-only	ENDPOINT_SUMMARY. MetabolismInLivestock. LinkToRelevantStudyRecord.Results
Description of key information	Please make a statement whether the nature of residues in commodities of animal origin was sufficiently investigated in the context of the present dossier (according to the relevant data requirements and OECD TG 503) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Respective detailed parameters on the available key studies used for risk assessment should be reported in a table format. Please use the recommended format, available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.2.2].	Header 1	ENDPOINT_SUMMARY. MetabolismInLivestock. KeyInformation
		Rich text area	ENDPOINT_SUMMARY. MetabolismInLivestock. KeyInformation.KeyInformation
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. MetabolismInLivestock. Discussion
	Provide additional information related to the endpoint, for example: - information on the	Rich text area	ENDPOINT_SUMMARY. MetabolismInLivestock. Discussion.Discussion

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	<p>potential data gaps</p> <ul style="list-style-type: none"> - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>		
Attached background material			ENDPOINT_SUMMARY.MetabolismInLivestock.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.MetabolismInLivestock.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty	Text	ENDPOINT_SUMMARY.MetabolismInLivestock.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	Add any additional document that supports the above key information (e.g. calculation tables,		

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	graphs). The depicted metabolic pathways can be uploaded here.		
Attached (sanitised) documents for publication	<p>Add any additional document that support the above key results (e.g. calculation tables, graphs). The overview of metabolism studies [cf. residue Template 6.2 (http://doi.org/10.5281/zenodo.4621089)] can be uploaded here by the applicant, although not mandatory. The uploaded file should not contain confidential material. Please note that the overview of the metabolism studies (excel file) will be generated later by the EMS/RMS during the risk assessment phase, provided that all MSS-composer xml-files of the metabolism studies are available to the RMS/EMS.</p>	Attachments list	ENDPOINT_SUMMARY. MetabolismInLivestock. Discussion.AttachedSanitisedDocsForPublication

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6.2.2 Metabolism of residues in livestock (incl. fish) – Endpoint study record

Purpose:

The results of the studies of metabolism in livestock are used to elucidate the degradation pathway of the active ingredient and require the identification of the metabolism and/or degradation products when a pesticide is applied to a crop directly or indirectly.

Studies of metabolism in livestock fulfil several major purposes:

- 1) provide an estimate of total terminal residues in edible animal products;
- 2) identify the major components of the total terminal residue in edible animal products;
- 3) indicate the distribution of residues between relevant edible animal products;
- 4) provide evidence whether or not a residue should be classified as fat soluble;
- 5) quantify the total residue in certain animal products (milk or eggs) and excreta;
- 6) quantify the major components of the residue and to show the efficiency of extraction procedures for these components;
- 7) characterise and quantify conjugated and bound residues;
- 8) indicate the components to be analysed for in residue quantification studies (livestock feeding studies);
- 9) generate data from which a decision on the need for feeding studies on food producing animals can be made

Currently, the general recommendation is to use a separate tool ("MSS composer") to report metabolism studies. Therefore, detailed parameters concerning the materials and methods and the results of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out all the fields in the present document.

However, the fields marked as "mandatory" in this document shall be fulfilled in IUCLID to ensure a minimum structured data and to make best use of the report generator.

The XML-files created with the MSS-composer should be uploaded in IUCLID as defined in this chapter and as defined in the general workflow for metabolism studies (see support material).

ENDPOINT_STUDY_RECORD.MetabolismInLivestock v.6.7			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource
Reference	Indicate the bibliographic reference of the study report or publication the study summary is based on. Select item from	Literature reference list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource.Reference

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	<p>'Literature Reference' database or create 'New Reference'.</p> <p>If you entered in the study in the MSS composer, the XML-files created with the MSS-composer should be attached in the LITERATURE object, to which reference is made here. These XML-files shall contain all the data fields on material and methods and on results and discussions that were not directly reported in the present study record.</p> <p>In the field "attached documents", please use the function "select files" and attach here each XML-file associated to study referred to in this LITERATURE OBJECT.</p> <p>If you did not enter yourself the study in the MSS composer because the XML-files linked to this study record already exist (and are available to the Regulatory Authorities), the attachment of the XML-files is not mandatory. In such a case, please report the corresponding individual file number in the field "other study identifier(s)" to help the Regulatory Authority</p>		
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	identifying the corresponding file(s) in the database.		
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.DataSource.Data Access
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.DataSource.DataProtectionClaimed
Materials and methods	<p>Material and methods – common block</p> <p>This part of the metabolism study should mainly be reported in a separate tool which is the “MSS composer”. Therefore, all detailed parameters concerning the materials and methods of the metabolism studies should be contained in the XML-file created with the “MSS-composer” and there is no need to fill out all the fields in the present section. However, the fields marked as “mandatory” shall be fulfilled to ensure a minimum structured data and to make best use of the report generator</p>	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods
Background information	Mandatory field.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.BackgroundInformation
Product type	Field not mandatory. The product type is already reported in	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLive

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	Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.		stock.MaterialsAndMethods.ProductType
Type of study	Mandatory field.	Open list	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TypeOfStudy
Test guideline	Mandatory field.		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.MethodNoGuideline
GLP compliance	Mandatory field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block This part of the metabolism study	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials

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	should be reported via the "MSS composer". However, test material information and specific details on test material used for the study shall be entered here to link the present study record to the test materials created in this dataset.		
Test material information	Mandatory field	Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study	Mandatory field	Text template	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)	Mandatory field	Text template	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidentialia
Radiolabelling	Mandatory field. Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.Radiolabelling
Radiolabelled test material	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial

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Radiolabel no	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial
SMILES notation	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SMILESNotation
Radiochemical purity(%)	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.RadiochemicalPurity
Specific activity as received	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityAsReceived
Specific activity of dose	Mandatory field. To be also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityOfDose
Remarks	Field not mandatory. Use this field to enter any remarks	Text	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.Remark

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Radiolabelled test material			
Test animals		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestAnimals
General test animal information	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation
Other details on housing conditions and test animals	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestAnimals.DetailsOnHousingConditionsAndTestAnimals
Test animal dietary regime	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestAnimals.TestAnimalDietaryRegime
Other details on dietary regime	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.TestAnimals.DetailsOnDietaryRegime
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.AdministrationExposure
Test animal dosing regime	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime

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Other details on dosing	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text template	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.AdministrationExposure.DetailsOnDosing
No. of animals per dose group	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerDoseGroup
Rationale for selection of dose group	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.AdministrationExposure.RationaleForSelectionOfDoseGroup
Analysis of feed and water	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.AdministrationExposure.AnalysisOfFeedAndWater
Further details on study design	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.AdministrationExposure.FurtherDetailsOnStudyDesign
Sampling and analysis		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.SamplingAndAnalysis
Sample collection	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection

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	in the XML-file attached to this record).		
Details on sampling	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnSamplingAndAnalyticalMethods
Details on extraction and analysis	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnExtractionAndAnalysis
Details on identification and characterisation	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnIdentificationAndCharacterisation
Flowchart of extraction and fractionation schemes	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes
Appendix: Treatment groups	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.AppendixTreatmentGroups
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>Field not mandatory. In this field, you can enter any information on materials and</p>	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

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	<p>methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>		
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion
Total radioactive residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.TotalRadioactiveResidues
Extraction efficiency of radioactive residues using enforcement method	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod
Quantitation	Field not mandatory.	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLive

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	To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		stock.ResultsAndDiscussion.TotalRadioactiveResidues.Quantitation
TRR results	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults
TRRs reached plateau at end of dosing	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Open list	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsReachedPlateauAtEndOfDosing
TRRs as a function of time	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsAsAFunctionOfTime
Graphical plot of TRRs as a function of time	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.TotalRadioactiveResidues.GraphicalPlotOfTRRsAsAFunctionOfTime
Other details on total radioactive residues (TRRs)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.TotalRadioactiveResidues.TotalRadioactiveResidues
Extraction, characterisation, and distribution of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.ExtractionCharacte

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			risationAndDistributionOfResidues
Distribution of parent and metabolites	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites
Other details on distribution of residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfResidues
Storage stability of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.StorageStabilityOfResidues
Summary of storage conditions	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions
Storage stability of residues (Sample integrity)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.StorageStabilityOfResidues.StorageStability
Summary of characterisation and identification of radioactive residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues
Proposed metabolic pathway		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscus

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			tion.ProposedMetabolic Pathway
Identification of compounds from metabolism study	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.ProposedMetabolic Pathway.IdentificationOfCompoundsFromMetabolismStudy
Identification of compounds from metabolism study	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		
Appendix: Metabolites and their parents in treatment groups	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups
Any other information on results incl. tables	Field not mandatory. In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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	'Executive summary' allow rich text entry.		
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RE CORD.MetabolismInLive stock.OverallRemarksAt tachments
Overall remarks	<p>Field not mandatory. In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>If you entered in the study in the MSS composer and/or if the XML-file created with the MSS-composer is available to you, please generate a word report from the MSS-composer (using the adequate feature in the MSS-composer software) and copy/paste this report in this field. Additional text can be added to complement the basic report generated by the MSS-composer.</p>	Rich text area	ENDPOINT_STUDY_RE CORD.MetabolismInLive stock.OverallRemarksAt tachments.RemarksOnR esults
Attached background material	Attach any background document that cannot be inserted in any rich text editor field,		ENDPOINT_STUDY_RE CORD.MetabolismInLive stock.OverallRemarksAt

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	particularly image files (e.g. an image of a structural formula).		tachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.OverallRemarksAt tachments.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.OverallRemarksAt tachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.OverallRemarksAt tachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.OverallRemarksAt tachments.IllustrationPicGraph
Attached (sanitised) documents for publication		Attachments list	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.OverallRemarksAt tachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ApplicantSummaryAndConclusion
Conclusions	Mandatory field. Write here the Applicant's conclusion of the metabolism study in context of the application.	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLive stock.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Mandatory field.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLive

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	Briefly summarise the relevant aspects of the study including the conclusions reached in the context of the application.		stock.ApplicantSummaryAndConclusion.ExecutiveSummary
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Links to support material:

Please find specific instructions on who to structure the results of metabolism studies plants and livestock under the following link:

<https://www.efsa.europa.eu/en/applications/pesticides/tools>

From the page, users will find all instructions to download the MSS composer (part of the Metapath software package), link to the technical manual for the MSS-composer, detailed information on the data flow for metabolism studies and access to the databases of metapath files.

Specific instructions on the process workflow for metabolism data are available in the following document: <https://zenodo.org/record/4785179#.YMjEe6gzbD4>"

6.3 Magnitude of residues in plants – Endpoint summary

Endpoint summary for “PRIMARY CROPS”:

Purpose:

To provide a summary overview of the residue levels of all components of monitoring (MO) and risk assessment (RA) residue definitions (RD) in the relevant commodities for the critical GAP(s), to summarize risk assessment values and the MRL proposals and to conclude whether the magnitude of residues in plant (primary crops) was sufficiently elucidated in the context of the present dossier.

ENDPOINT_SUMMARY.MagnitudeResiduesPlants v.1.2 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation

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	Please make a statement whether the magnitude of residues in plant (primary crops) was sufficiently elucidated in the context of the present dossier (according to the relevant data requirements and to OECD TG No 509) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Respective detailed parameters on the available key trials used for risk assessment should be reported in the repeatable block "Summary of residues data from the supervised residue trials", following the instructions below.	Rich text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.KeyInformation
Summary of residues data from the supervised residue trials	Repeat this block to create one "new item" per GAP under assessment.		ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData
Study name / type	Provide here the link to the relevant study(ies) used to derive the endpoints (HR, STMR, MRL...) reported in this table.	Endpoint reference list	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Link
Relevant GAP	Link to the critical GAP from which the MRL and risk assessment values are derived.	Endpoint reference list	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.RelevantGap
Commodity(ies) for which MRL and risk assessment values are derived	Please select from the picklist the commodity(ies) of plant origin to which MRLs apply according to Part A of Annex I of	Multi select open list	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.CommodityForMrl

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	<p>Regulation (EC) 396/2005. The picklist contains also relevant feed items, to be selected when residue trials provide data on residues in feed items. For feed items not listed, select `Other` and specify.</p>		
<p>Commodity(ies) used in the residue trials</p>	<p>Please select from the picklist the commodity(ies) of plant origin according to Part A and B of Annex I of Regulation (EC) 396/2005 on which the residue trials were performed (multi-selection is possible) The picklist contains also relevant feed items, to be selected when residue trials provide data on residues in feed items, used to derive STMR, HR and CF for feed items. For feed items not listed, select `Other` and specify.</p>	<p>Multi select open list</p>	<p>ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Commodity</p>
<p>Residue levels: RD RA</p>	<p>Report here all results from supervised residue trials for one crop raw agricultural commodity (RAC), e.g. for wheat grain, including the components of the residue definition for risk assessment (RA). Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The</p>	<p>Multi-line text</p>	<p>ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResidueLevelsRiskAssessment</p>

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	<p>residue values below LOQ shall be indicated. For chemicals, values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.02; 0.03; 0.03; 0.05; 0.06; 0.23.</p>		
Residue levels: RD MO	<p>If residue definition (RD) for risk assessment (RA) and RD for monitoring are different, please report here all results from supervised residue trials relevant for each RAC, e.g. for wheat grain, including the components of the residue definition for monitoring. Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated. For chemicals, values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.02; 0.03; 0.03; 0.05; 0.06; 0.23.</p>	Multi-line text	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.ResidueLevelsMonitoring
Mean conversion factor (CF)	<p>If RD for RA differ from RD for monitoring insert here the mean conversion factor (CF). $CF = \frac{[\text{residue concentration according to RD-RA}]}{[\text{residue concentration according RD-MO}]}$ To derive the mean CF, you need to derive the</p>	Decimal	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.MeanConversionFactor

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	CF for each pair of results (RD-RA/RD-MO) individually and to calculate the average of the series of values.		
Highest residue	Enter supervised trials highest residue value (HR) [default unit is mg/kg]	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.HighestResidue
STMR	Enter supervised trials median residue value (STMR) [default unit is mg/kg]	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Stmr
MRL derived	Enter here the MRL as derived from the submitted residue trials for the commodities listed under `Commodity(ies) for which MRL and risk assessment values are derived`. Not mandatory for commodities exclusively used as feed items (e.g. wheat straw).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.MrIDerived
Remarks	Please insert here any other remarks, if necessary, relevant for the residue trials data. If the results reported in the block refer to single trial results for pulp (e.g. orange pulp), this should be specified here in the remarks: e.g. "detailed results and risk assessment values derived from pulp". In such a case, no MRL needs to be derived.	Text area	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Remarks

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Results applicable to	Select "primary plant".	Multi select closed list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResultsApplicableTo
Summary of residues data from the supervised residue trials			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion
	Use this field to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.Discussion
Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).		ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs). In support of the MRLs calculated for plant commodities, please also attach here the	Attachments list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedSanitisedDocsForPublication

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	<p>OECD calculator Excel, available for single and multiple data sets here: https://www.oecd.org/env/ehs/pesticides_biocides/oecdmaximumresiduelimitcalculator.htm.</p> <p>If additional calculators (e.g. Kruskal-Wallis.xls to compare dataset) were used in the assessment, they should also be uploaded here</p> <p>The uploaded file should not contain confidential material.</p>		
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Endpoint summary for “ROTATIONAL CROPS”:

Purpose:

Provide a summary overview of the residue levels of all components of monitoring (MO) and risk assessment (RA) residue definitions (RD) in the relevant rotational crops at various plant back intervals (PBI) covering the maximum soil concentration expected for the active substance (and its soil metabolites) for the use pattern on primary crop under assessment, to summarize risk assessment values and the MRL proposals (if relevant) and to conclude whether the magnitude of residues in rotational crops was sufficiently elucidated in the context of the present dossier and whether restrictions in crop rotation are required.

ENDPOINT_SUMMARY.MagnitudeResiduesPlants v.1.2 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary.DataProtection

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Description of key information		Header 1	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation
	<p>Please make a statement whether the magnitude of residues in rotational crops was sufficiently elucidated in the context of the present dossier (according to the current data requirements and to OECD TG 504) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Please indicate here:</p> <p>1) Whether significant residues are expected in rotational crops, in the context of the present application (i.e. based on the GAP on primary crops under assessment). If no: please provided rationale. If yes: please specify if specific studies investigating the magnitude of residues in rotational crops were reported.</p> <p>2) If specific studies on the magnitude of residues in rotational crops were reported, please make a statement: - as to whether the study parameters cover the maximum soil concentration expected for the active substance (and its soil</p>	Rich text area	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation

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	<p>metabolites), considering the use pattern on primary crop under assessment.</p> <p>- as to whether those studies can be used to derive MRL and risk assessment values (HR and STMR). Respective detailed parameters and results on the eventual available key trials used for risk assessment should be reported in the detailed table below.</p>		
Summary of residues data from the supervised residue trials	Repeat this block to create one box per crop group for which risk assessment value and MRLs may be derived from rotational crops.		ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData
Study name / type	Provide here the link to the relevant study(ies) used to derive the endpoints (HR, STMR, MRL...) reported in this table.	Endpoint reference list	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Link
Relevant GAP	Please select the GAP considered for the assessment of magnitude of residues in rotational crops (e.g. the GAP on primary crop leading to highest residues in soil in the next growing season).	Endpoint reference list	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.RelevantGap
Commodity(ies) for which MRL and risk assessment values are derived	Please select from the picklist the commodity of plant origin to which MRLs apply according to Part A of Annex I of Regulation (EC) 396/2005.	Multi select open list	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.CommodityForMrl

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	<p>The picklist contains also relevant feed items, to be selected when residue trials provide data on residues in feed items. For feed items not listed, select `Other` and specify.</p>		
<p>Commodity(ies) used in the residue trials</p>	<p>Please select from the picklist the commodity of plant origin according to Part A and B of Annex I of Regulation (EC) 396/2005 on which the residue trials were performed.</p> <p>The picklist contains also relevant feed items, to be selected when residue trials provide residue data in feed items, used to derive STMR, HR and CF for feed items. For feed items not listed, select `Other` and specify.</p>	<p>Multi select open list</p>	<p>ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Commodity</p>
<p>Residue levels: RD RA</p>	<p>Report here all results from supervised residue trials for one crop RAC, e.g. for wheat grain, including the components of the residue definition for risk assessment. Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be</p>	<p>Multi-line text</p>	<p>ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.ResidueLevelsRiskAssessment</p>

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	<p>indicated. Values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.02; 0.03; 0.03; 0.05; 0.06; 0.23.</p>		
Residue levels: RD MO	<p>If RD for RA and RD for monitoring differ report here all results from supervised residue trials for one crop RAC, e.g. for wheat grain, including the components of the residue definition for monitoring. Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated (for example, <0.01 mg/kg). Values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.02; 0.03; 0.03; 0.05; 0.06; 0.23.</p>	Multi-line text	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.ResidueLevelsMonitoring
Mean conversion factor	<p>If RD for RA differ from RD for monitoring insert here the mean conversion factor (CF). CF= [residue concentration] according to RD-RA / [residue concentration] according RD-MO To derive the mean CF, you need to derive the CF for each pair of results (RD-RA/RD-MO) individually and to calculate the average of the series of values.</p>	Decimal	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.MeanConversionFactor

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Highest residue	Enter supervised trials highest residue value (HR) [default unit is mg/kg]	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.HighestResidue
STMR	Enter supervised trials median residue value (STMR) [default unit is mg/kg]	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Stmr
MRL derived	If MRL is derived, please enter here the MRL as derived from the submitted residue trials for the commodities listed under `Commodity(ies)` for which MRL and risk assessment values are derived`. Not mandatory for commodities exclusively used as feed items (e.g. wheat straw).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.MrIDerived
Remarks	Please insert here any other remarks, if necessary. Please specify which PBI (plant back interval) and which eventual mitigation measures were considered to derive the endpoints above. Indicate whether a rotational crop was planted/sown following a treatment and harvest of primary crop. Indicate whether the proportionality principle was applied to derive the key endpoints (HR, STMR, MRL) and how the scaling factors were	Text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Remarks

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	<p>derived (e.g. based on soil samples analysis compared to plateau expected concentration (PEC) calculated for the critical GAPs under assessment). Please elaborate on the approach used to derive the MRL proposal and risk assessment values for rotational crops and indicate if any extrapolations are proposed.</p>		
Results applicable to	<p>Select "rotational crops". Optional: If results are given for the aggregated residues or primary and rotational crops, please select both "primary plant", "rotational crops".</p>	Multi select closed list	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.ResultsApplicableTo
Summary of residues data from the supervised residue trials			
Additional information	<p>Discussion(Header 1) – common block</p>	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.Discussion
	<p>Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.</p>	Rich text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.Discussion.Discussion
Attached background material	<p>Add any additional document that support the above key results</p>		ENDPOINT_SUMMARY.MagnitudeResiduesPlans.Discussion.AttachedBackgroundMaterial

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	(e.g. calculation tables, graphs).		
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	<p>Add any additional document that support the above key results (e.g. calculation tables, graphs).</p> <p>In support of the MRLs calculated for plant commodities, please also attach here the OECD calculator Excel, available for single and multiple data sets here: https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm</p> <p>The uploaded file should not contain confidential material.</p>	Attachments list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedSanitisedDocsForPublication

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6.3 Magnitude of residues in plants - Endpoint study record

Purpose:

- Primary crops: Magnitude of residue trials in plants shall allow to quantify the highest likely residue levels of all components of the different residue definitions in treated crops at harvest or outloading from store, in accordance with the proposed GAP, and, to determine, where appropriate, the decline rate of plant protection product residues in plants.
- Rotational crops: Magnitude of residue trials in rotational crops shall permit an evaluation of the magnitude of residues in rotational crops, to decide on restrictions in crop rotation, provide information for assessing the overall relevancy of the residues for dietary risk assessment and to decide on the necessity of MRLs for rotational crops

ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops v.6.7 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.DataProtection
Endpoint	For primary crop supervised residue trials select `residues in crops (field trials)` For rotational crop studies select `residues in rotational crops (limited field studies)`	Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.PurposeFlag
Study period		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.StudyPeriod

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Reliability		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.CrossReference

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Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.Administrativ eData.CrossReference. ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.Administrativ eData.CrossReference. RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.Administrativ eData.CrossReference. Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.DataSource
Reference		Literature reference list	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.DataSource. Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.DataSource. DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.DataSource. DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.ProductType
Test guideline			ENDPOINT_STUDY_RE CORD.ResiduesInRotati

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			onalCrops.MaterialsAnd Methods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.Guideline.Qual ifier
Guideline		Open list	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.Guideline.Guid eline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.Guideline.Versi onRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.Guideline.Devi ation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.MethodNoGuid eline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.GLPComplianc eStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.TestMaterials. TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.TestMaterials.

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			SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy Confidential
Analytical methods		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods
Analytical method	If the method has been reported in Section 4 of the dossier 'Analytical methods', please refer to it, providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and contain the data on method validation, further information is not required		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod
Method ID	Create an ID for the method. This ID should be used in the summary of the residue trials to unambiguously refer to the method used in the trial. In the field "related information", please create a link towards the study record of the used analytical method and its validation. If the study record referred to is duly compiled and contain the data on method validation, the	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.MethodID

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	rest of this block is not required.		
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.RelatedInformation
Details on analytical methods		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.DetailsOnAnalyticalMethods
Combinations of substance and analysed sample portion			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.AnalyteIdentity
Analysed sample portion ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.AnalysedSamplePortionID
Analysed sample portion description		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.AnalysedSamplePortionDescription

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			lysedSamplePortionDescription
Fortification			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.Fortification
Fortification level		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.Fortification.FortificationLevel
Recovery (%)		Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.Fortification.Recovery
Fortification			
Combinations of substance and analysed sample portion			
Analytical method			
Residue trials	This field contains detailed information of supervised residue trials on primary crops performed according to the critical GAP. For rotational crops the residue trials reflect the accumulation of residues in rotational crops via soil uptake following the realistic	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern

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	agricultural practices on primary crops.		
Trial ID no.	Insert the trial specific, unequivocal identification code	Text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialIdNo
Trial information	<p>Option 1: Possibility to use the repeatable block to report individual trial information. Copy this block of fields for recording the results of each sampling. This option could be deployed in case of small data sets.</p> <p>Option 2: Report the detailed residue trial information directly in the Excel file Residues trial table to be attached in the field below "Attached sanitized documents" (See detailed instructions in "Attached sanitized documents").</p> <p>For option 2, any additional information which is relevant for the residue trial but not captured in the Excel residue trial tables should be reported in the field `Any other information on materials and methods, incl.tables`.</p>		ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation
Geographic location and soil characteristics		Header 3	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Geo

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			graphicLocationAndSoil Characteristics
Test site type		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.TestSite Type
Geographic location		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.GeographicLocation
Trial deviation		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.TrialDeviation
Year		Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.Year
Country or territory		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.Country
Geographic region		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil

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			Characteristics.GeographicRegion
State/Province		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.StateProvince
County		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.County
City		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.City
GPS coordinates		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.GPSCoordinates
Type of crop		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TypeOfCrop
Type of trial		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil

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			Characteristics.TypeOfT rial
Crop grouping (primary)		Open list	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Geo graphicLocationAndSoil Characteristics.CropGro upingPrimary
Crop group		Open list with remarks	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Geo graphicLocationAndSoil Characteristics.CropGro up
Crop		Text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Geo graphicLocationAndSoil Characteristics.Crop
Crop code		Text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Geo graphicLocationAndSoil Characteristics.CropCod e
Crop variety		Text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Geo graphicLocationAndSoil Characteristics.CropVari ety
Replant no. (1, 2)		Integer	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Geo

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			graphicLocationAndSoil Characteristics.Replant No
Date of planting		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.DateOfPlanting
Date of seeding		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.DateOfSeeding
Date of flowering (beginning)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.DateOfFloweringBeginning
Date of flowering (end)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.DateOfFloweringEnd
Date of harvest (beginning)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.DateOfHarvestBegin
Date of harvest (end)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd

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			Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfHarvestEnd
Crop plant back interval		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropPlantBackInterval
Crop information / history		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropInformation
Soil characterization		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.SoilCharacterization
Other details on test crops		Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.OtherDetailsOnTestCrops
Plot description		Header 3	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription
Plot			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd

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			Methods.StudyUsePattern.TrialInformation.PlotDescription.Plot
Plot ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.PlotID
Control plot		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.ControlPlot
Corresponding control plot ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.CorrespondingControlPlotID
Plot description		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.PlotDescription
Environmental conditions		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.EnvironmentalConditions
Other details on test site		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.DetailsOnTestSite
Application		Header 4	ENDPOINT_STUDY_RECORD.ResiduesInRotati

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			onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion
Application			ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application
Application no. (1, 2)		Integer	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.Applicat ionNo
Bare soil		Closed list	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.BareSoi l
Growth stage code (BBCH) at application		Text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.Growth StageCode
Growth stage description at application		Text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.Growth Stage
Date of application		Date	ENDPOINT_STUDY_RE CORD.ResiduesInRotati

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			onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.DateOf Application
Method of application		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.Method OfApplication
Seeding rate		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.Seeding Rate
Thousand grain weight		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.Thousa ndGrainWeight
Applied test material			ENDPOINT_STUDY_RECORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte m
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte

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			m.TestMaterialInformation
Description of test item		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.DescriptionOfTestItem
Formulation type		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.FormulationType
Trade name		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.TradeName
Active ingredients (a.i.)			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients
Related substance information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.RelatedSubstanceInfo
Name of a.i.		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotati

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			onalCrops.MaterialsAnd Methods.StudyUsePatter n.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte m.ActiveIngredients.Na meOfAI
Nominal a.i. content		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatter n.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte m.ActiveIngredients.No minalAIContent
Applied amount (actual)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatter n.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte m.ActiveIngredients.Ap pliedAmountActual
Amount a.i./seed (actual)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatter n.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte m.ActiveIngredients.Am ountAISEedActual
Applied amount (cumulative nominal)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatter n.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte m.ActiveIngredients.Ap pliedAmountCumulative
Adjuvant added		Multi-line text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd

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			Methods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AdjuvantAdded
Amount of water used in spray application (nominal)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AmountOfWaterUsedInSpray
Active ingredients (a.i.)			
Applied test material			
Application			
Other details on application		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.OtherDetailsOnApplication
Sampling		Header 4	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalyticalMethodology
Details on sample collection		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalyticalMethodology.DetailsOnSampleCollection

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Details on sample handling and preparation		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndPreparation
Sampling and analysis of soil		Header 4	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil
Details on sampling of soil		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil.DetailsOnSamplingOfSoil
Details on analytical methodology for soil residues		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil.DetailsOnAnalyticalMethodologyForSoilResidues
Plot			
Trial information			
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>In this field, you can enter any information on materials and methods, for which no distinct field is</p>	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

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	<p>available, or which could not be reported in the Excel residue trial tables or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document. For example, tables summarizing the details on sampling time (age of crop in days) for rotational crop RACs; stages of crop development at each sampling point (e.g., at forage hay and grain stages), number of samples/replicates. For rotational crop trials if soil residues were determined, in `Sampling and analysis of soil` include details on the sampling, sampling method and handling and preparation of soil samples.</p>		
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion

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<p>Storage stability of residues (Sample integrity)</p>	<p>Where samples were not analysed within 30 days, provide evidence showing that the storage did not affect the results of the study. Provide here the information on how long the residue field samples were stored prior to analysis and under which conditions. Specify whether the conditions of storage of the samples of the present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated. Provide justification for deviations, if any. Typically, reference should be made to Section 6.1 where storage stability data showing the behaviour of residues as a function of time in plant commodities have been reported. By reference to the endpoint summary on storage stability (Section 6.1), please specify whether the conditions of storage of the samples of the present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.StorageStability</p>
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Summary of residues	Option 1: Possibility to use the repeatable block to report individual results, for each sampling and for each relevant analyte. Copy this block of fields for recording the results of each sampling. This option could be deployed in case of small data sets. Option 2: Report the detailed residue trial information directly in the Excel file Residues trial table to be attached in the field below "Attached sanitized documents" (See detailed instructions in "Attached sanitized documents").	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops
Sampling and residues			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues
Trial ID no.		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.TrialIDNo
Plot ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.PlotID

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Sampling ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SamplingID
Sampling timing		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SamplingTiming
Growth stage code (BBCH) at sampling		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.GrowthStageCode
Growth stage description at sampling		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.GrowthStage
Date of sampling		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.DateOfSampling
Sampling information		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SamplingInformation
Sampled material / commodity (Field RAC sample) code		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRa

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			dioactiveResiduesInCrops.SamplingAndResidues.SampledMaterialCommodity
Sampled material / commodity (Field RAC sample) description		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SampledMaterialCommodityDescription
Residue levels			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels
Method ID		Link to repeatable entry	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.MethodID
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.AnalyteIdentity
Analysis sample portion ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.AnalysisSampleDescription
Extraction date		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDi

IUCLID ACTIVE SUBSTANCE APPLICATION MANUAL

			scussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.AnalysisDate
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.StorageStabilityFactor
Use of storage stability factor		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.UseOffactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.Recovery

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Correction by recovery		Closed list	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ResultsAndDi scussion.SummaryOfRa dioactiveResiduesInCro ps.SamplingAndResidue s.ResidueLevels.Correct ionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ResultsAndDi scussion.SummaryOfRa dioactiveResiduesInCro ps.SamplingAndResidue s.ResidueLevels.Refere ncePortion
Residue level (measured)		Range with open list (Decimal)	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ResultsAndDi scussion.SummaryOfRa dioactiveResiduesInCro ps.SamplingAndResidue s.ResidueLevels.Residu eLevelMeasured
Calculated analyte identity		Entity reference field	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ResultsAndDi scussion.SummaryOfRa dioactiveResiduesInCro ps.SamplingAndResidue s.ResidueLevels.Calcula tedAnalyteIdentity
Residue level (calculated)		Range with open list (Decimal)	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ResultsAndDi scussion.SummaryOfRa dioactiveResiduesInCro ps.SamplingAndResidue s.ResidueLevels.Residu eLevelCalculated
Residue level (calculated and corrected)		Range with open list (Decimal)	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ResultsAndDi scussion.SummaryOfRa dioactiveResiduesInCro ps.SamplingAndResidue

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			s.ResidueLevels.ResidueLevelCorrected
Residue levels			
Total / mean		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.TotalMean
Sampling and residues			
Any other information on results incl. tables	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document.	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments

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			ksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication	<p>If you did not use the option 1 to report the detailed results for each sample, please upload here the Excel file Residues trial table (primary and rotational crops).</p> <p>An empty template of the Excel file Residues trial table (primary and rotational crops) is available on the 'knowledge junction' [cf. residue Template 6.3 (http://doi.org/10.5281/zenodo.4621116)].</p>	Attachments list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedSanitisedDocsForPublication

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	The uploaded file should not contain confidential material.		
Applicant's summary and conclusion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion
Interpretation of results	Select applicable conclusion from the picklist	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion.InterpretationOfResults
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion.Conclusions
Executive summary	<p>The assessment and conclusion of the applicant should be reported here.</p> <p>Briefly summarise the relevant aspects of the study(ies) including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document.</p> <p>Example for supervised residue trials on primary crops: [Number] field trials for [active ingredient] on [crop(s)] were conducted in [country] during the [year] growing season. At each trial location, [describe timing and method of application; formulation used, rate, treatment interval and seasonal application</p>	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion.ExecutiveSummary

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	<p>rates of [xx] g ai/ha]. An adjuvant [was or was not] added to the spray mixture for all applications. [Crops] were harvested at a preharvest interval (PHI) of [xx] days. In [one] trial, samples were collected at different time intervals (PHIs of x, xx, xxx days) to monitor residue decline. All samples were maintained frozen at the testing facility, during shipping to the laboratory, and were stored frozen until analysis. The maximum storage interval for samples between harvest and analysis was [xx] days/months. Residues of [active ingredient] have been shown to be stable in [crops] for up to [xx] days under frozen conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current trials. Samples in the current study were analyzed using Method [Method ID], a [describe method] to determine residues of [list analytes]. Acceptable [method validation and]</p>		
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	<p>concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] per analyte for [matrices]. Individual sample (and per-trial average) residues in [matrix] ranged from [xx] mg/kg to [yy] mg/kg. [Include for each matrix and/or variation in use pattern in the study]. Residue decline data show that residues of [active ingredient/metabolite] [increase/decrease/are unchanged/are too variable to assess decline] in [commodities] with increasing PHIs.</p> <p>Example for rotational crop field trials: [Number] field trials for [active ingredient] on [crop(s)] as rotational crops were conducted in [country] during the [year] growing season. At each trial location, [describe timing and method of application (specify bare soil or primary crop); formulation used, rate, treatment interval and seasonal application rates of [xx] g ai/ha).</p>		
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	<p>An adjuvant [was or was not] added to the spray mixture for all applications. [Describe growth/maintenance of primary crop, if applicable]. [Crops] were planted into treated plots at plant-back intervals (PBIs) of [xx, yy, and zz] days. Crops were harvested at maturity and prepared for residue analysis.</p> <p>All samples were maintained frozen at the testing facility, shipped and stored frozen until analysis. The maximum storage duration for samples between harvest and analysis was [xx] days/months. Residues of [active ingredient] have been shown to be stable in [crops] for up to [xx] days under frozen conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current trials.</p> <p>Samples in the current study were analyzed using Method [Method ID], a [describe method] to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries</p>		
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	<p>were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] mg/kg per analyte for [matrices]. The results from these trials show that quantifiable residues of [list analytes] are not expected to occur at PBIs greater than [xx] days. At a PBI of [yy] days, individual sample residues ranged from [xx] ppm to [yy] ppm (Crop 1), [xx] ppm to [yy] ppm (Crop 2), and [xx] ppm to [yy] ppm (Crop 3). [Address other PBIs as needed.]</p>		
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6.4 Feeding studies – Endpoint summary

Purpose:

To provide a summary overview of the residue levels of all components of enforcement (MO) and risk assessment (RA) residue definitions (RD) in the relevant animal matrix for the calculated livestock dietary burdens, to summarize risk assessment values and the MRL proposals and to conclude whether the magnitude of residues in products of animal origin was sufficiently elucidated in the context of the present dossier.

Fill in the 'Description of key information' field. Expected key information: MRL proposals, median and highest residue levels (STMR and HR) for each animal matrix (i.e muscle, fat, liver, kidney, milk, eggs, etc). Please make use of the Animal calculator Excel to derive these end points using the results of the feeding studies (i.e. residue concentrations for each dose level) and comparison with dietary burden calculation. The animal calculator.xls should be uploaded as an attachment.

ENDPOINT_SUMMARY.ResiduesLivestock v.1.1 (Final)

Name	Instructions	Type	Field path
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Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ResiduesLivestock.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.ResiduesLivestock.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.ResiduesLivestock.LinkToRelevantStudyRecord
Study name / type	Provide here the link to the most relevant study(ies) from which the key values for magnitude of residues in commodities of animal origin are derived.	Endpoint reference list	ENDPOINT_SUMMARY.ResiduesLivestock.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.ResiduesLivestock.LinkToRelevantStudyRecord.Results
Description of key information		Header 1	ENDPOINT_SUMMARY.ResiduesLivestock.KeyInformation
	Please make a statement whether the magnitude residues in commodities of animal origin was sufficiently investigated in the context of the present dossier (according to the current data requirements and OECD GD on residues in livestock, Series on Pesticides No 73) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Please indicate here:	Rich text area	ENDPOINT_SUMMARY.ResiduesLivestock.KeyInformation.KeyInformation

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	<p>1) Whether significant residues are expected in commodities of animal origin, in the context of the present application (i.e. based on the critical GAPs under assessment).</p> <p>If no: please provided rationale.</p> <p>If yes: please specify if specific studies investigating the magnitude of residues in livestock commodities were reported. 2) If specific studies on the magnitude of residues in livestock commodities were reported, please make a statement as to whether the study were used to derive MRL and risk assessment values in commodities of animal origin.</p>		
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. ResiduesLivestock.Discussion
	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY. ResiduesLivestock.Discussion.Discussion
Attached background material	Add any additional document that support the above key results		ENDPOINT_SUMMARY. ResiduesLivestock.Discussion.AttachedBackgroundMaterial

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	(e.g. calculation tables, graphs).		
Attached document		Single file attachment	ENDPOINT_SUMMARY.ResiduesLivestock.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.ResiduesLivestock.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	<p>Add any additional document that support the above key results (e.g. calculation tables, graphs). Please upload the Excel file which was eventually used to:</p> <ol style="list-style-type: none"> 1) Calculate the livestock dietary burden (DB) relevant for the present application (including detailed input values and detailed results for each group of livestock). 2) Report the detailed results of the livestock feeding studies used to assess the magnitude of residues in commodities of animal origin (those studies that are cross-referred in the above block). 3) Calculate MRLs and risk assessment values for all animal tissues and products 	Attachments list	ENDPOINT_SUMMARY.ResiduesLivestock.Discussion.AttachedSanitisedDocsForPublication

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	<p>based on 1 and 2, in the context of the present application. Please attach the "Excel Animal calculator" available on knowledge junction [cf. residue Template 6.4 (https://doi.org/10.5281/zenodo.661713)]. This Excel file is essential for the EMS/RMS to understand which input values were used to assess the livestock DB and how study results were considered by the Applicant to support the above key results. RMS/EMS may modify it during the risk assessment phase. The uploaded file should not contain confidential material.</p>		
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6.4 Feeding studies – Endpoint study record

Purpose:

Residues in Livestock studies are conducted in order to quantify levels of residues in meat, milk, eggs and edible meat by-products (e.g. fat, liver, kidney), following the use of a pesticide product on feed plant commodities. The studies are conducted according to OECD TG 505 and provide data on the quantitative transfer of residues, i.e. factor between residue level in the diet and residue levels in edible commodities (milk, eggs, tissues).

Residues in Livestock studies are typically conducted in ruminants (cattle) and poultry (laying hen). In general, the results of cattle feeding studies may be extrapolated to other domestic animals (ruminants, horses, pigs, rabbits and others) and laying hen feeding studies to other types of poultry (turkey, goose, duck and others). Please create one Endpoint study record per feeding study. Extrapolations should be specified in the endpoint summary above.

If feeding studies are not required in the context of the present application, please specify

NB: If you used a metabolism study as a proxy to conclude that residues exceeding the LOQ are expected in some matrices or if the calculated intakes indicate that existing MRLs have to be changed, additional calculations based on the livestock feeding study data have to be performed in order to set/update the MRL values for products of animal origin.

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ENDPOINT_STUDY_RECORD.ResiduesInLivestock v.6.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist, here: "Residues in livestock"	Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.Reliability

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Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference.ReasonPurpose

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Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource
Reference		Literature reference list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods
Background information		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.BackgroundInformation
Product type	The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.ProductType

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	resistance). This field is optional.		
Type of study		Open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TypeOfStudy
Test guideline			ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.GLPComplianceStatement

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Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Test animals		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals
Species	Select name of species. Multiple selection is possible, but it is strongly recommended to use separate records for each animal species studied. You can include a cross-reference, in field 'Same study also described in chapter:', to the record where the methodology is described in detail.	Multi select open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals.Species

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<p>Details on housing conditions and test animals</p>	<p>Include details on housing conditions and test animals. Use free text template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). The following information should be addressed: HOUSING / HOLDING AREA: Describe the test facilities, i.e. animal housing including size of enclosures, individual vs. group housing, food and water containers, temperature, lighting, and waste handling. TEST ANIMALS: Include information on breed, age, weight, stage of development, health status and condition of test animals.</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnHousingConditionsAndTestAnimals</p>
<p>Details on dietary regime</p>	<p>Include details on dietary regime. Use free text template and delete/add elements as appropriate, upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnDietaryRegime</p>

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	<p>study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>The following information should be addressed:</p> <ul style="list-style-type: none"> - Composition of diet: Describe the diet of animals during acclimation and the dosing period regarding: <ol style="list-style-type: none"> (1) Types of feed (e.g., corn grain, layers mash, alfalfa pellets) and liquids; (2) Quantities provided (i.e., specific amounts or ad libitum). - Feed consumption: Report the feed consumption (dry weight for ruminants) on an individual or treatment group basis throughout the study. - Water: Report water consumption - Acclimation period: specify 		
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure
Treatment type (route of exposure)	Select the treatment type used which determines the primary route of exposure in the study. Multiple	Multi select open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExpos

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	<p>selection is possible if, in specific situations, direct application of a product to livestock was studied in addition to exposure through feeding of treated crops.</p> <p>Most frequent options in the context EU PPP assessments: Oral: "capsule" or "applied on feed"</p>		<p>ure.TreatmentTypeRouteOfExposure</p>
Duration and frequency of dosing	<p>Indicate the total length of the dosing period (e.g. 20 days) including withdrawal periods where applicable, and the frequency of application / dosing if the test material is not incorporated into the total diet or feed.</p>	Multi-line text	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DurationAndFrequencyOfDosing</p>
Doses / concentrations	<p>Indicate the dose rates (feeding levels) as "mg/kg bw per day" (also possible mg/kg diet, mg/animal/day). If diet is the route of administration, the level of the test material in the total diet may be reported in parts per million (mg/kg feed) (dry weight basis for ruminants).</p>	Multi-line text	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposures.DosesConcentrations</p>
Details on dosing	<p>Include further details on the preparation of dose and the dosing regimen. If diet is the route of administration, use free text template (delete/add elements as appropriate) or</p>	Text template	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DetailsOnDosing</p>

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	<p>formulate otherwise or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>PREPARATION OF DOSE: Describe the method of preparation of the dose (mixing with feed or concentrate ration, gelatine capsule, bolus, etc.). Indicate the date of dose preparation and storage conditions prior to its administration.</p> <p>RATIONALE FOR SELECTION OF DOSE LEVELS: Briefly describe, i.e. Level of intake expected, Exaggerated levels. Provide justification for other than the recommended dosing scheme.</p> <p>ANALYSIS OF SPIKED FEED: Describe the method used to analyse spiked feeds and the results of such analyses. If the methodology is described in chapter 'Analytical methods', you can include a cross-reference to that</p>		
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	record in the block 'Cross-reference'. DOSING REGIME: Using an appropriate predefined table indicate the dosing regimen used.		
No. of animals per dose group	Report the number of animals per dose group, e.g. 3 cows per feeding level.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerDoseGroup
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Further details on study design		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.FurtherDetailsOnStudyDesign
Further details on study design	Include any further relevant details on the study design.	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.FurtherDetailsOnStudyDesign.FurtherDetailsOnStudyDesign
Details on sampling and analytical methods	Include details on the sampling, handling and preparation of samples and the analytical methodology applied. Use freetext template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.FurtherDetailsOnStudyDesign.DetailsOnSamplingAndAnalyticalMethods

	<p>study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>The following information should be addressed:</p> <p>IN-LIFE SAMPLING</p> <ul style="list-style-type: none"> - Milk / eggs collected: Explain the collection of milk and eggs with any deviations from normal practice explained. Note compositing or pooling of samples; no pooling of milk from animals within a dosage group. - Amount of milk and number of eggs produced during normal production: Provide data as indicated. - Urine, faeces, cage wash collected: For feed-through pesticides, include data on urine, feces and cage wash. <p>POST-SLAUGHTER SAMPLING</p> <ul style="list-style-type: none"> - Mode of sacrifice: Describe - Interval from last dose or treatment to sacrifice: Describe the 		
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	<p>time interval in hours or days between time of sacrifice and administration of last dose or application of final treatment. Give an explanation of intervals longer than 24 hours and consideration of their effect on residues.</p> <ul style="list-style-type: none"> - Tissue harvested and their weights: Indicate the tissues taken after sacrifice, their type (e.g., thigh muscle, omental fat, etc.), and their weights. - Specification of and combining of samples from different animals: Indicate if pooling was done (usually acceptable for poultry, but not ruminants). <p>SAMPLE HANDLING AND PREPARATION: Describe the handling of tissues, eggs and milk between sample collection and storage addressing at least following items:</p> <ul style="list-style-type: none"> - Sample preparation prior to storage: e.g., chopping - Containers - Storage temperature - Length of storage: Include dates of 		
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	<p>collection, shipping, analysis, etc.</p> <ul style="list-style-type: none"> - Mode of shipping, if applicable: <p>ANALYTICAL METHODOLOGY</p> <p>The method and its validation should be reported in Section 4 of the dossier 'Analytical methods', using a specific study record. Please cross-refer to the analytical methods and its validation providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and contain the data on method validation, further information is not required. In the study record created for this method (and its validation) in Section 4 of the dossier, the following information is expected:</p> <ul style="list-style-type: none"> - Description of instrumentation, equipment and reagents used: Give a detailed description of the analytical method employed to measure residues and listing of which 		
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	<p>chemical species were measured (parent pesticide, metabolites). If the methodology is described in chapter 'Analytical methods', you can include a cross-reference to that record in the block 'Cross-reference'.</p> <ul style="list-style-type: none"> - Extraction schemes: state 'see graphic attached' if a figure is attached in field 'Illustration (picture/graph)' in 'Overall remarks, attachments'. - Description of extraction and fractionation of radioactivity in each matrix - Chromatographic and spectroscopic behaviour of radioactive residues in extracts of animal matrices, parent, metabolites, and reference standards - The LOQ for all animal matrices analysed and, if available, the LOD and a description of how the LOQ and LOD were determined. 		
<p>Any other information on materials and methods incl. tables</p>	<p>Any other information on materials and methods incl. tables - (H2) – common block</p>	<p>Header 2</p>	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AnyOtherInformatio</p>

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			nOnMaterialsAndMethodsInclTables
	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion
Storage stability	Where samples were not analysed within 30 days, provide evidence showing that the storage did not affect the results of the study. Typically, reference should be made to Section 6.1 where storage stability data showing the behaviour of residues as a function of time in tissues, milk, and eggs have been reported. By reference to the endpoint summary on storage stability	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.StorageStability

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	(Section 6.1), please specify whether the conditions of storage of the samples of the present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated.		
Residue data	<p><u>Option 1:</u> Possibility to use the repeatable block to report individually the residue levels, for each tissue at each sampling time for each feeding level for each relevant analyte. Copy this block of fields for recording the results of each sampling.</p> <p><u>Option 2:</u> If more convenient, you may skip this field and directly report the detailed results in the field below "Any other information on the results including tables". In such a case, simply copy/paste free text and Table(s) (see detailed instructions below).</p>		ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData
Sampling no.		Multi select closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.SamplingNo
Matrix / tissue sampled		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.MatrixTissueSampled

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Sampling time		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.SamplingTime
Dose / feeding level		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.DoseFeedingLevel
Residue levels			ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.AnalyteIdentity
Residue level (measured)		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.ResidueLevelMeasured
Residue level (calculated)	Not needed	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.ResidueLevelCalculated
Residue level (calculated and corrected)	Not needed	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.ResidueLevelCorrected
Remarks		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.Remarks

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Residue levels			
Total / mean	Specify the total (mean) of the parent compound and the metabolites, for instance if the residue definition was determined for enforcement purposes.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.TotalMean
Residue data			
Recoveries	Provide recovery percentages (all values, not just averages or ranges) for the test substance and/or its metabolites for tissues, milk, and eggs fortified with these compounds. If the method is described in another record, you can include a reference to that method description using the 'Cross-reference' feature. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.Recoveries

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<p>Depuration</p>	<p>Provide the results of depuration studies, if any. If a separate depuration study was done, you can include a reference to that record using the 'Cross-reference' feature. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.Depuration</p>
<p>Residue transfer</p>	<p>Outline the conclusion reached as to whether residues of the pesticide transfer from feed items, direct application to meat, milk and eggs. If so, discuss the extent of transfer. Indicate the time needed to reach a plateau level in eggs and milk, respectively. The results can be summarized in a table (the preferable format) showing either the ranges or maximum residues in type each of sample for each feeding level. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueTransfer</p>

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	study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').		
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. If you did not use the option 1 to report the detailed results for each sample, please report it in one/several table(s) of results. Please use the recommended formats, available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.4]. Please repeat the tables as much as necessary.	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments

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Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.RemarksOnResults
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file. <u>Do not</u> upload the "Excel Animal calculator" here as this should be done at the level of the endpoint summary.		ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedBackgroundMaterial.Attached Document
Remarks		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedStudy Report
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.IllustrationPic Graph

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Attached (sanitised) documents for publication		Attachments list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ApplicantSummaryAndConclusion
Conclusions	Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any).	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ApplicantSummaryAndConclusion.Conclusions
Executive summary	<p>Briefly summarise the relevant aspects of the study including the conclusions reached.</p> <p>Example: [Active ingredient] was administered [method of administration] to [number and breed] of [animal] for [duration] consecutive days. Dosing was made at [list dosing levels in mg/kg feed]. [Report details on depuration study, if applicable.]</p> <p>Milk/egg samples were collected twice daily [provide details on sampling method]. Animals were sacrificed on Day xx within [xx] hours of last dose. Tissue samples of [liver, kidney, muscle, and fat] were taken from each sacrificed animal. All samples were maintained frozen at the testing facility,</p>	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ApplicantSummaryAndConclusion.ExecutiveSummary

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	<p>during shipping to the laboratory and were stored frozen until analysis. The maximum storage interval for samples between collection and analysis was [xx] days/months. Residues of [active ingredient] have been shown to be stable in [livestock matrices] for up to [xx] days under frozen conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current study.</p> <p>Samples in the current study were analysed using Method [Method ID], a [describe method] to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] ppm, thus validating the method. The limit of quantitation (LOQ) was [xx] ppm per analyte for [matrices].</p> <p>Following a pre-slaughter interval of [xx] hours, individual sample residues ranged from xx ppm to yy ppm</p>		
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	<p>[list matrices and residue levels]. [Describe, qualitatively and quantitatively, the relationship between residue levels and dosing levels for the matrices addressed in the study.] Depuration results indicated that residues of [analytes(s)] will [describe depuration results, noting especially matrices where there appears to be little reduction of residues with time.]</p>		
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6.5 Effects of processing – Endpoint summary

Purpose:

Purpose of document on the effects of processing on the nature of residues: To provide a summary on the nature of the active substance/metabolites under standard hydrolysis study and to conclude whether or not breakdown or reaction products arise from residues in the raw agricultural commodity (RAC) during processing, which may require a separate risk assessment.

Purpose of document on the effects of processing on the magnitude of residues: To provide an overview on the quantitative distribution of residues in various processed commodities (PC) and the derived processing factors (PF). Pesticide residues to be measured in processing studies are determined by the residue definition which is derived from studies on the nature of the residue in processing and/or in plant and livestock.

ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities v.1.4 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommoditi

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			es.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation
	<p>Please make a statement whether:</p> <p>1) the nature of residues in processed commodities was sufficiently investigated in the context of the present dossier (according to current data requirements and OECD Guideline No 507) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Please also clarify if the reported conclusions on stability/non stability of the residues under hydrolytic conditions refer to the parent compound only and/or to any relevant metabolites found in plant and animals. In the latter case, please create the endpoint summary in the metabolite data set and specify the metabolites covered by this conclusion.</p> <p>2) the magnitude of residues in processed commodities was sufficiently investigated in the context of the present dossier (according to current</p>	Rich text area	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.KeyInformation

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	<p>data requirements and to OECD Guideline No 508) and highlight data gap(s) and the non-standard uncertainty(ies), if any.</p> <p>Key results used for the risk assessment should be reported in the detailed tables below.</p>		
Nature of residues in processed commodities	Repeat this block to create one row per key result (e.g. one row for each hydrolytic condition investigated by the study/ies).		ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities
Relevant studies	Provide here the link to the most relevant study(ies) from which the key results for nature of residues in processed commodities.	Endpoint reference list	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.RelevantStudies
Conditions	Select the standard hydrolysis conditions (e.g. sterilisation) for which a conclusion can be derived.	Multi select open list with remarks (2000)	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.Conditions
Stable	Select a statement whether the residues are stable or not when undergoing hydrolytic conditions mentioned above. Please use the field "remark" to further specify the conclusion (e.g. if the answer is "no", please specify which are the main degradation products expected, e.g. if the answer is "inconclusive", please	Closed list with remarks (2000)	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.Stable

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	specify the eventual data gaps).		
Nature of residues in processed commodities	Repeat this block to create one row per key result (e.g. one row for each hydrolytic condition investigated by the study/ies).		
Processing factors	<p>Repeat this block to create one box per combination raw agricultural commodity (RAC)/processed commodity (PC) for which processing factors could be derived.</p> <p>This section can also be used to capture the distribution of residues in peel/pulp by derivation of process factor pulp/RAC.</p>		ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors
Relevant studies	Provide here the link to the most relevant study(ies) from which the key values (e.g. processing factors) for magnitude of residues in process commodities are derived.	Endpoint reference list	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.RelevantStudies
Raw agricultural commodity (RAC)	<p>Raw agriculture commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing. The term RAC means the same as "primary food commodity" or "primary feed commodity".</p> <p>Indicate the raw agricultural commodity</p>	Open list with remarks (2000)	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.RawCommodity

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	<p>(RAC) for which the processing factor is derived (e.g. apple).</p> <p>If not available, select 'other:' and specify.</p>		
Processed commodity (PC)	<p>Processed commodity (PC) means the products - resulting from the application of physical, chemical or biological processes or combinations of these to a "primary food commodity" - intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing. A primary processed commodity is derived from mechanical or chemical processing of the RAC and is not a multicomponent product.</p> <p>Indicate the processed commodity (PC) for which the processing factor is derived (e.g. apple juice). If not available, select 'other:' and specify.</p>	Open list with remarks (2000)	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.ProcessedCommodity
Number of trials	Indicate here the number of independent tests used to derive processing factors.	Integer	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.NoTrials
Median processing factor: RD MO	Processing factor (PF) is the ratio of the residue level identified in the processed commodity according to	Decimal	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.Proc

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	<p>the residue definition for enforcement (RD MO) and the residue level identified in the raw agricultural commodity according to enforcement residue definition (RD MO):</p> $PF\ MO = \frac{[residue\ concentration\ in\ Processed\ Com]}{[residue\ concentration\ in\ RAC]}\ RD\ MO$ <p>This factor is valid for the combination `procedure/commodity`, which was investigated in the processing study.</p> <p>Insert here the mean (of two studies) or median (of more than 2 studies) value of all available processing factors for a given combination raw agricultural commodity (RAC)/processed commodity (PC).</p> <p>If the residue definition for enforcement purposes in processed products differs from the residue definition in the RAC, the processing factor should be calculated taking into account the molecular weights of the different substances. If that is not feasible, the</p>		<p>essingFactors.ProcessingFactorMo</p>
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	processing factors shall reflect the enforcement residue definition in processed commodity.		
Median processing factor: RD RA	<p>Insert here the mean (of two studies) or median (of more than 2 studies) value of all available processing factors for a given combination raw agricultural commodity (RAC)/processed commodity (PC) according to following formula:</p> $PF\ RA = \frac{[residue\ concentration\ in\ Processed\ Com]\ RD\ RA}{[residue\ concentration\ in\ RAC]\ RD\ MO.}$ <p>If the residue definition for risk assessment purposes in processed products differs from that in the RAC, the processing factor should be calculated taking into account the molecular weights of the different substances. If that is not feasible, the processing factors shall reflect the risk assessment residue definition in processed commodity.</p>	Decimal	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.ProcessingFactorRa
Remarks	Please enter any additional remark for the processing factor, for example if the	Multi-line text	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.Remarks

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	processing factor is tentative.		
Processing factors			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.Discussion
	<p>This section can be used to add any additional useful text.</p> <p>A discussion could be provided as to the significance of the residues in the processed commodities and the distribution behavior of the active ingredient and metabolite/degradation products, i.e., in which processed commodities and at what levels quantifiable residues can be expected. Comparison of processing factors should also be discussed if two or more tests are conducted within one study and described in one final report.</p> <p>If there is no additional information to be reported this field may be left empty.</p>	Rich text area	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.Discussion.Discussion
Attached background material	You can attach here any useful document that support the above statement. However, do not repeat the attachments that are already reported in the		ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.Discussion.Attached BackgroundMaterial

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	respective endpoint summaries of the detailed sections.		
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs).	Attachments list	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.Discussion.AttachedSanitisedDocsForPublication

6.5.1 Nature of the residue – Endpoint study record

<p>Purpose: Studies concerning the nature of the residue to establish whether or not breakdown or reaction products arise from residues in the raw agricultural commodity (RAC) during processing, which may require a separate risk assessment.</p>

ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod v.4.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist:	Closed list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesI

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	<p>- Nature of the residues in processed commodities: high temperature hydrolysis. Or - Nature of the residues in processed commodities: other. If `other` is selected, please specify in the remark field the type of the study.</p>		nProcessedCommod.AdministrativeData.Endpoint
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.ProductType
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.TestMaterials
Radiolabelling	Select the appropriate product from the picklist (yes; no; other;; not specified). Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field	Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.TestMaterials.Radiolabelling

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	'Specific details on test material'. Any other useful information to include in the remark field.		
Study design		Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.StudyDesign
Test strategies	Brief description of testing guideline conditions used.	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.StudyDesign.TestStrategies
Experimental procedure	Describe experimental procedure applied by using the existing templates. Brief outline of study design, i.e. test facility, environmental/hydrolytic conditions, amount and concentrations of test substance applied, use of solvent, etc. Use freetext template and delete/add elements as appropriate. If applicable, discuss unusual experimental problems encountered, attempts made to alleviate these problems which resulted in deviations from the intended test protocol and the effects, if any, of those deviations on the results of the study.	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.StudyDesign.ExperimentalProcedure
Sampling and analytical methodology		Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.Sam

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			plingAndAnalyticalMethodology
Details on sample handling and storage conditions	<p>Include details on the sampling, sample handling and storage conditions. The following information should be addressed: handling and shipping of commodities, storage conditions, length of storage, any preparation done prior to extraction. Use the existing templates to report the necessary information.</p>	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommoditiesAndMaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndStorageConditions
Details on analytical methodology	<p>If the method has been reported in Section 4 of the dossier 'Analytical methods', please refer to it, providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and contain the data on method validation, further information is not required.</p> <p>If no study record was created for this method (and its validation) in Section 4 of the dossier, you have 2 options how to report the data: Option 1: please use the existing templates to report the following details on analytical method: method validation data,</p>	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommoditiesAndMaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology

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	<p>recovery and method sensitivity data. Preparation and handling of the sample throughout the method described in detail. Note that methods for metabolites may also be needed. Recovery data should be obtained concurrently with the residue analyses to validate the method and establish its sensitivity (lowest reliable quantification limit). State the LOD and LOQ. Experimental design of these validation studies described including: (1) Identity of the test compounds and crop substrates, (2) Magnitudes of fortification levels, (3) Number of replicates per test compound per level. Identify instrumentation, equipment and reagents used and the operating conditions of the instrumentation. If the extraction/clean-up procedure is complex, a flow diagram should be submitted.</p> <p>Option 2: Summarize the details on analytical methodology in table(s) as reported in the field `Any other information on materials and methods incl.tables`</p>		
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<p>Any other information on materials and methods incl. tables</p>	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document. For reporting details on analytical methodology, if you did not use Option 1, please report here the details on the analytical methods in one/several table(s). Please use the recommended formats as available in the knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.462183), Table 6.5].</p>	<p>Header 2</p>	<p>ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables</p>
		<p>Rich text area</p>	<p>ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation</p>
<p>Results and discussion</p>		<p>Header 1</p>	<p>ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion</p>

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<p>Storage stability (Sample Integrity)</p>	<p>Please provide a statement on the sample integrity against storage conditions. Where relevant, provide storage stability data for all major components of the total radioactive residues, including conditions and length of storage of samples following receipt in laboratory and conditions and length of storage of extracts prior to identification of residues.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.StorageStability</p>
<p>Total radioactive residues (TRR)</p>	<p><u>Option 1:</u> possibility to use the repeatable block to report individual results for each identified compound per test condition. Copy this block of fields for recording the results for each test compound per test condition. <u>Option 2:</u> report directly the detailed information on the results of hydrolysis study and on the identity of TRR components in table(s) in the field `Any other information on results incl. tables`.</p>		<p>ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR</p>
<p>TRR component no.</p>		<p>Closed list</p>	<p>ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRComponentNo</p>

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Test conditions		Multi-line text	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TestConditions
Identity of TRR component		Entity reference field	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.IdentityOfTRRComponent
TRR concentration		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRConcentration
TRR percentage		Range (Decimal)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRPercentage
Total radioactive residues (TRR)			
Other details on TRRs	Provide any other relevant details related to the characterisation and/or identification and distribution of TRRs.	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.OtherDetailsOnTRRs
Metabolic pathway	Discuss the routes of degradation observed and describe the metabolic pathways and/or attach figures in field "Illustration (picture/graph)"	Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.MetabolicPathway
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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	<p>In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. If you did not use the option 1 to report the detailed results for each analyte determined for given processing condition, please report it in one/several table(s) of results. Please use the recommended formats, available in [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.5].</p>	Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached.	Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ApplicantSummaryAndCon

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	<p>Example: The effect of processing on the nature of [active substance/metabolite] was investigated in standard hydrolysis study simulating [include here the process, temperature, pH] conditions. The results showed that the [active substance/metabolite] is hydrolytically stable OR progressively degrades to [indicate degradation product, % applied radioactivity, amount in mg/kg] OR almost totally degraded to [indicate degradation product, % applied radioactivity, amount in mg/kg] under [indicate processing condition]. Further considerations on the nature of identified degradation products, if any, could be provided here.</p>		<p>clusion.ExecutiveSummary</p>
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6.5.3 Magnitude of residues in processed commodities – Endpoint study record

<p>Purpose: Studies concerning the effects of processing on the magnitude of residues in processed commodities to determine the quantitative distribution of residues in the various processed commodities used as food or feed, to estimate processing factors and to allow a more realistic estimation of dietary intake of residues.</p>
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ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm v.4.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidI

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			nProcessedComm.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist: magnitude of residues in processed commodities	Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.AdministrativeData.Reliability

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Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.CrossReference

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Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.DataSource
Reference		Literature reference list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible	Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.ProductType

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	resistance). This field is optional.		
Test guideline			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.Mate

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			rialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Study design		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.MaterialsAndMethods.StudyDesign
Bulk raw agricultural commodity (RAC)	Raw agriculture commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing, or for processing into food for sale to the consumer. The term RAC means the same as "primary food commodity" or "primary feed commodity". Select the raw agricultural commodity (RAC). If not available,	Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.MaterialsAndMethods.StudyDesign.BulkRawAgriculturalCommodity

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	select 'other:' and specify.		
Details on test commodity	Include details on the test commodity, including a description of the general condition (e.g. immature/mature, green/ripe, fresh/dry). Use existing template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.StudyDesign.DetailsOnTestCommodity
Sample processing	Briefly describe how the RAC was processed into the processed commodity(ies). As appropriate and relevant, attach or upload the processing flow chart in 'Illustration (picture/graph)'.	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.StudyDesign.SampleProcessing
Further details on study design	Include any further relevant details on the study design. Use existing templates and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.StudyDesign.FurtherDetailsOnStudyDesign
Sampling and analytical methodology		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology
Details on sample collection	Include details on sampling time (age of raw commodity in days), number of samples/replicates. Use existing templates and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleCollection
Details on sample handling and preparation	Include details on the sample handling and preparation. Use existing template and	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.Sampli

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	delete/add elements as appropriate. The following information should be addressed: handling and shipping of commodities, storage conditions, length of storage, any preparation done prior to extraction.		ngAndAnalyticalMethodology.DetailsOnSampleHandlingAndPreparation
Details on analytical methodology	<p>The analytical method and its validation should be reported in a specific study record, created in Section 4 of the dossier 'Analytical methods'. Please refer to it, providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and contain the data on method validation, further information is not required.</p> <p>Please make sure that the following details on analytical method are duly reported: method validation data, recovery and method sensitivity data. Preparation and handling of the sample throughout the method described in detail. Note that methods for metabolites may also be needed. Recovery data should be obtained concurrently with the residue</p>	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology

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	<p>analyses to validate the method and establish its sensitivity (lowest reliable quantification limit). State the LOD and LOQ. Experimental design of these validation studies described including: (1) Identity of the test compounds and crop substrates, (2) Magnitudes of fortification levels, (3) Number of replicates per test compound per level. Identify instrumentation, equipment and reagents used and the operating conditions of the instrumentation. If the extraction/clean-up procedure is complex, a flow diagram should be submitted.</p>		
<p>Any other information on materials and methods incl. tables</p>	<p>Any other information on materials and methods incl. tables - (H2) – common block</p>	<p>Header 2</p>	<p>ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables</p>

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	<p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document. Please report here the details on the analytical methods that could not be reported in Section 4. Please use the recommended formats as available in [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.462183), Table 6.5].</p>	Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion
Storage stability of residues (Sample integrity)	<p>Provide storage stability data for all major residues, including conditions and length of storage of samples following receipt in laboratory and conditions and length of storage of extracts prior to identification of residues (Note: Handling, pre-shipping storage and shipping procedures for harvested samples to be described in field</p>	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.StorageStabilityOfResiduesSampleIntegrity

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	'Details on sampling and analytical methodology').		
Residues in RAC prior to processing		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing
Bulk RAC sub-sample sample no.	<p>Option 1: possibility to use the repeatable block to report individual results for each RAC. Copy this block of fields for recording the results for each test compound per test condition. This option could be deployed in case of small data sets.</p> <p>Option 2: report directly the detailed information on the results in RAC in the Excel file Processing trials table [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)] to be attached in the field below "Attached background material"</p>		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo

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Date of sub-sample		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.DateOfSubSample
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalysisSampleID
Analysis sample description		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalysisSampleDescription
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleS

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			ampleNo.AnalyteMeasur ed.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInRACPriorToProcessi ng.BulkRACSubSampleS ampleNo.AnalyteMeasu red.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInRACPriorToProcessi ng.BulkRACSubSampleS ampleNo.AnalyteMeasu red.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInRACPriorToProcessi ng.BulkRACSubSampleS ampleNo.AnalyteMeasu red.StorageStabilityFact or
Use of factor		Text	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInRACPriorToProcessi ng.BulkRACSubSampleS ampleNo.AnalyteMeasu red.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInRACPriorToProcessi ng.BulkRACSubSampleS ampleNo.AnalyteMeasu red.CorrectionByStorag eStability
Recovery		Decimal	ENDPOINT_STUDY_RE CORD.MagnitudeResidI

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			nProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.CorrectionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ReferencePortion
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ResidueLevelMeasured
Residue level (calculated)	Not needed	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ResidueLevelCalculated
Residue level (calculated and corrected)	Not needed	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessi

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			ng.BulkRACSubSampleSampleNo.AnalyteMeasured.ResidueLevelCalculatedAndCorrected
Analyte measured			
Bulk RAC sub-sample sample no.			
Residues in processed fractions (PF) and aspirated grain fractions (AGF)		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF
Processing information	Description of processing method(s). Processed fraction: Special attention should be given to, but not limited to, processing order, pressures, temperatures, and the corresponding yield-weights of each fraction. Processed fraction handling (e.g. samples were frozen within 24 hours after processing). A description of the process method is necessary and the use of flow chart diagrams is helpful.	Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessingInformation
Processed fraction	Option 1: possibility to use the repeatable block to report individual results for each processed commodity/fraction. Copy this block of fields for recording the results for each test compound per test condition. This option		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction

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	could be deployed in case of small data sets. Option 2: report directly the detailed information on the results for each processed commodity/fraction in the Excel file Processing trials table [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)] for residues in processed commodities to be attached in the field below "Attached sanitized documents"		
Processed fraction (PF sample)		Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedCommoditiesAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.PFSample
PF sample no.		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedCommoditiesAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.PFSampleNo
Date of processing		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedCommoditiesAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.DateOfProcessing
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidual

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			nProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.ProcessedFractio.AnalysisSampleID
Analysis sample description		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.ProcessedFractio.AnalysisSampleDescription
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.ProcessedFractio.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.ProcessedFractio.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.ProcessedFractio.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.Residu

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			esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .CorrectionByStorageSt ability
Recovery		Decimal	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu

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			esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .CorrectionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .ReferencePortion
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .ResidueLevelMeasured
Residue level (calculated)	Not needed	Range with closed list (Decimal)	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAndAspiratedGrainFr actionsAGF.ProcessedFr action.AnalyteMeasured .ResidueLevelCalculated
Residue level (calculated and corrected)	Not needed	Range with closed list (Decimal)	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions

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			PFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResidueLevelCalculatedAndCorrected
Analyte measured			
Processed fraction			
Aspirated grain fractions (AGF sample)	<p>Option 1: possibility to use the repeatable block to report individual results for each AGF sample. Copy this block of fields for recording the results for each test compound per test condition. This option could be deployed in case of small data sets.</p> <p>Option 2: report directly the detailed information on the results for each AGF sample in the Excel file Processing trials table [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)] for residues in processed commodities to be attached in the field below "Attached sanitized documents".</p>		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample
AGF analysis sample		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AGFAnalysisSample
Date of AGF sample		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidI

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			nProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.DateOfAGFSample
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidinProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalysisSampleID
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidinProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidinProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidinProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ExtractionDate

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Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.Metho dID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.Stora geStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.UseOf Factor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFr

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			actionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.CorrectionByRecovery
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelMeasured
Residue level (calculated)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelCalculated

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Residue level (calculated and corrected)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelCalculatedAndCorrected
Analyte measured			
Aspirated grain fractions (AGF sample)			
Distribution of residues	Report quantitative information on the recovery of the residue from the processed commodities.	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.DistributionOfResidues
Any other information on results incl. tables	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.	Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidI

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			nProcessedComm.Over allRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.Over allRemarksAttachments .RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.Over allRemarksAttachments .AttachedBackgroundM aterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.Over allRemarksAttachments .AttachedBackgroundM aterial.AttachedDocume nt
Remarks		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.Over allRemarksAttachments .AttachedBackgroundM aterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.Over allRemarksAttachments .AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.Over allRemarksAttachments .IllustrationPicGraph
Attached (sanitised) documents for publication	Please upload here the Excel file Processing trials table. An empty Excel file to report Residues in Processed commodities is available on the 'knowledge junction'	Attachments list	ENDPOINT_STUDY_RECORD.MagnitudeResidI nProcessedComm.Over allRemarksAttachments .AttachedSanitisedDocs ForPublication

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	[cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)]. The uploaded file should not contain confidential material.		
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ApplicantSummaryAndConclusion.Conclusions
Executive summary	<p>Briefly summarise the relevant aspects of the study including the conclusions reached. Example:</p> <p>[crop] field trial for [active ingredient] was conducted in [country, location] during the [year] growing season. [Active ingredient, % ai, formulation type] was applied to [crop] at [rate of application (xx g ai/ha)] and harvested xx days after final treatment. The [RAC samples] were processed into [processed food/feed fractions] using [simulated commercial practices].</p> <p>All samples were frozen at the testing facility and remained frozen during shipping and</p>	Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ApplicantSummaryAndConclusion.ExecutiveSummary

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	<p>storage prior to processing and analysis. The maximum storage interval for samples was [xx] days/months [specify period from harvest to processing and from processing to analysis]. Storage conditions and durations are supported by studies showing that residues of [active ingredient] are stable in [crops/processed commodities] for up to [xx] days under frozen conditions.</p> <p>Samples in the current study were analyzed using Method [Method ID], a [describe method] method to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] mg/kg per analyte for [matrices].</p> <p>A comparison of the residues in the raw agricultural commodity (RAC) with those in each processed fraction resulted in processing factors of [processing</p>		
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	factors] for [processed fractions], respectively. These processing factors [conform/did not conform] with the theoretical concentration factors.		
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6.7 Proposed residue definitions and maximum residue level

6.7.1 Proposed residue definitions – Endpoint summary

Purpose:

provide a summary overview on the residue definitions for commodities of plant and animal origin as derived on the basis of available metabolism studies in plant, livestock and processed commodities; and to provide conclusions on which compounds are to be included in the residue definitions for enforcement and risk assessment. In this endpoint summary, you should also highlight the tentative/indicative residue definitions and their relevant data gaps.

ENDPOINT_SUMMARY.ResidueFood v.1.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ResidueFood.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.ResidueFood.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.ResidueFood.KeyInformation
	Optional text box to specify any particular issue related to the residue definitions, that could not be reported in the following tables.	Rich text area	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.KeyInformation
Food / feed of plant origin residue definition risk assessment	Use the repeatable block to create as many rows as necessary to reflect each combination “crop group/metabolism group/treatment		ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa

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	<p>type/provisional or not” residue definitions for risk assessment derived for this substance. Please make sure that a residue definition for risk assessment is proposed for all combinations that are relevant for this application</p>		
Crop group	<p>Indicate if the residue definition covers primary crops and/or processed and/or rotational. Please make sure that a residue definition for risk assessment is proposed for each item of the picklist, unless not required (e.g. not relevant for rotational crops)</p>	<p>Multi select closed list with remarks</p>	<p>ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.CropGroup</p>
Metabolism group	<p>If the residue definition is for primary crops or rotational crops, then select the metabolism group for which the RD is applicable (from list OECD list Crops and Crop Groups for Purposes of Metabolism in Crops Studies)</p>	<p>Multi select open list with remarks</p>	<p>ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.MetabolismGroup</p>
Treatment type	<p>Indicate the type(s) of treatment for which the RD is applicable (e.g. seed treatment or foliar application)</p>	<p>Multi select open list with remarks</p>	<p>ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.TreatmentType</p>
Residue definition risk assessment	<p>Write here the full name of the residue definition for risk assessment; please use the exact wording in line with the current standards (e.g. sum of</p>	<p>Multi-line text</p>	<p>ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.ResidueDefinitionRisk</p>

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	parent and metabolite 01, expressed as parent).		
Residue definition risk assessment components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.ResidueDefinitionRiskComp
Provisional	Indicate if the residue definition for risk assessment is provisional, if yes a remark field will open where the data gaps should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.Provisional
Remarks	Any additional remarks regarding the proposed RD for risk assessment (e.g. common RD with other substances, RD1 associated with tox references value of compound 1, RD2 associated with tox references value of compound 2...).	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.Remarks
Food / feed of plant origin residue definition risk assessment			
Food / feed of plant origin residue definition for monitoring	Use the repeatable block to create as many rows as necessary to reflect each combination "metabolism group/provisional or not" residue definitions derived for this substance. Please note that for monitoring RD,		ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring

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	no distinction be made between primary and rotational crops.		
Metabolism group	Select the metabolism group for which the RD is applicable (from list OECD list Crops and Crop Groups for Purposes of Metabolism in Crops Studies)	Multi select open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.MetabolismGroup
Residue definition monitoring	Write here the full name of the residue definition for monitoring; please use the exact wording in line with the current standards (e.g. sum of parent and metabolite 01, expressed as parent).	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoring
Residue definition monitoring components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoringComp
Monitoring residue definition LOQ (mg/kg)	Limit of quantification (LOQ) for the residue definition for monitoring and enforcement	Decimal	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.MonitoringResidueDefinitionLoq
Provisional	Indicate if the residue definition for monitoring is provisional, if yes describe a remark field will open where the data gap(s) should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.Provisional
Remarks	Any additional remarks regarding the proposed RD monitoring (e.g.	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.Remarks

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	common RD with other substance(s)...))		
Validated method	Indicate if there is a validated method for Monitoring (including inter-laboratory validation ILV) is available	Check box	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.ValidateMethod
Link to validated method	Link to the study describing method for monitoring and its validation	Endpoint reference field	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.LinkToValidatedMethod
Food / feed of plant origin residue definition for monitoring			
Food of animal origin residue definition risk assessment	Use the repeatable block to create as many rows as necessary to reflect each combination "animal commodity/provisional or not" residue definitions for risk assessment derived for this substance.		ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa
Animal	Select the animal group (e.g ruminants) for which the proposed residue definition is applicable. If the same residue definition is applicable to several animals (e.g. ruminants and pigs), multi-selection feature can be used.	Open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Animal
Commodity	Select that animal product (e.g. liver or eggs) for which the proposed residue definition is applicable. Please make sure that a residue definition for risk assessment is	Multi select open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Commodity

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	proposed for each item of the picklist. If the same residue definition is applicable to several commodities (e.g. r all tissues of ruminants and pigs), multi-selection feature can be used.		
Residue definition risk assessment	Write here the full name of the residue definition for risk assessment; please use the exact wording in line with the current standards (e.g. sum of parent and metabolite 01, expressed as parent).	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.ResidueDefinitionRiskAssessment
Residue definition risk assessment components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.ResidueDefinitionRiskAssessmentComponents
Provisional	Indicate if the residue definition for risk assessment is provisional, if yes a remark field will open where the data gaps should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Provisional
Remarks	Any additional remarks regarding the proposed RD for risk assessment (e.g. common RD with other substances, RD1 associated with tox references value of compound 1, RD2 associated with tox	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Remarks

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	references value of compound 2...).		
Food of animal origin residue definition risk assessment			
Food of animal origin residue definition monitoring	Use the repeatable block to create as many rows as necessary to reflect each combination "animal commodity/provisional or not" residue definitions for monitoring derived for this substance.		ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring
Animal	Select the animal group (e.g ruminants) for which the proposed residue definition is applicable. If the same residue definition is applicable to several animals (e.g. ruminants and pigs), multi-selection feature can be used.	Open list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Animal
Commodity	Select that animal product (e.g. liver or eggs) for which the proposed residue definition is applicable. If the same residue definition is applicable to several commodities (e.g. r all tissues of ruminants and pigs), multi-selection feature can be used.	Multi select open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Commodity
Residue definition monitoring	Write here the full name of the residue definition for risk assessment; please use the exact wording in line with the current standards (e.g. sum of	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoring

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	parent and metabolite 01, expressed as parent).		
Residue definition monitoring components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoringComp
Monitoring residue definition LOQ (mg/kg)	Limit of quantification (LOQ) for the residue definition for monitoring and enforcement	Decimal	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.MonitoringResidueDefinitionLog
Provisional	Indicate if the residue definition for monitoring is provisional, if yes describe a remark field will open where the data gap(s) should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Provisional
Remarks	Any additional remarks regarding the proposed RD monitoring (e.g. common RD with other substance(s)...))	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Remarks
Validated method	Indicate if there is a validated method for Monitoring (including inter-laboratory validation ILV) is available	Check box	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.ValidatedMethod
Link to validated method	Link to the study describing method for monitoring and its validation	Endpoint reference field	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.LinkToValidatedMethod
Food of animal origin residue definition monitoring			

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Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ResidueFood.Discussion
	Provide any additional information, this can be in the format of tables	Rich text area	ENDPOINT_SUMMARY.ResidueFood.Discussion.Discussion
Attached background material	Upload any additional material to support the residue definition proposal		ENDPOINT_SUMMARY.ResidueFood.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.ResidueFood.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.ResidueFood.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A sanitised version of the attachment/s must be provided for publication	Attachments list	ENDPOINT_SUMMARY.ResidueFood.Discussion.AttachedSanitisedDocsForPublication

6.7.2 Proposed maximum residue levels – Flexible summary record

Purpose:

provide a summary overview on the proposed MRLs for commodities of plant and animal origin as derived on the basis of supervised residue field trials (for plants) or from livestock feeding studies (for animal commodities). In this endpoint summary, you should also highlight the tentative/indicative MRLs and their relevant data gaps, indicate the proposed extrapolations and discuss the eventual non-standard uncertainty.

FLEXIBLE_SUMMARY.MRLProposal v.1.1 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.MRLProposal.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.MRLProposal.Administrati

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			veDataSummary.DataProtection
Description of key information		Header 1	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation
	Optional text box to specify any particular issue related to the proposed MRL(s), that could not be reported in the following table.	Rich text area	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.KeyInformation
Maximum residue level	Use the repeatable block to create as many rows as necessary to report each MRL proposed in this application. Please report only one MRL proposal per combination "commodity/residue definition for monitoring". If for a given plant commodity, different MRLs could be derived in section 6.3 (based different GAPs), please only report the MRL to be proposed for inclusion in the Regulation (i.e. highest MRL for which no safety concerns are identified). A MRL proposal should be linked to a GAP, at least one commodity and to a residue definition for monitoring (RD MO). If more than one RD MO are derived for this active substance, please propose one MRL per RD MO.		FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel
Rationale for MRL proposal	Please indicate the reason why a new MRL	Open list with remarks (2000)	FLEXIBLE_SUMMARY.MRLProposal.KeyInforma

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	<p>is proposed, by choosing one or more rationale(s). Repeat this action for each MRL proposed in this table. Examples: - if an MRL on wheat grain is directly derived from a GAP on wheat, please select "use on primary crop". - If an MRL on commodity of animal origin is derived because the GAP on wheat leads to a significant increase of the dietary burden, please select "increase of the livestock dietary burden".</p>		<p>tion.MaximumResidueLevel.RationaleForMrl</p>
<p>Critical GAP</p>	<p>This entry refers to the critical GAP(s), on which the MRL proposal is based. If rationale for the MRL proposal is "use on primary crop", cross ref to the critical GAP. In case of several GAPs for the same commodity/crop (e.g. SEU, NEU, indoor, third countries) only one link to GAP resulting in the highest MRL proposal not leading to consumer safety concerns should be made. If the MRL proposal is based on a combined dataset linked to several GAPs, links to all these GAP forms should be made. If rationale for MRL proposal is "residue in rotational crops from</p>	<p>Endpoint reference list</p>	<p>FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.CriticalGap</p>

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	<p>soil uptake”, please cross refer to the GAP leading to highest residue in soil. it is noted that the cross-link to GAP may not yet work. If GAPs are not visible when clicking on the link, please let this field empty. If GAPs are visible please select the relevant GAP(s) as defined above.</p>		
Commodity	<p>Indicate the commodity(ies) for which MRL is derived. Please repeat this block for each MRL proposal. In case of extrapolations, with similar MRL for different commodities, the extrapolated commodities can be selected using the multi-selection (e.g. apples, pears, quinces).</p>	Multi select open list	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.Commodity
MRL proposal	<p>This field refers to the MRL proposal (in mg/kg) in the commodity(ie)y of plant or animal origin. In case of multiple GAPs, the highest MRL (expressed on RD for monitoring) and not leading to consumer safety concerns should be inserted here.</p>	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.MrlProposal
Residue definition monitoring	<p>Enter the monitoring residue definition relevant for the selected commodities of plant or animal origin. This is the</p>	Multi-line text	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.ResidueDefinitionMonitoring

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	residue definition on which the MRL is derived.		
MRL at LOQ	Tick this box to indicate if the MRL is proposed at the enforcement LOQ (equivalent to symbol * in the EU MRL database.	Check box	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.MrlLoq
Maximum residue level			
Additional information	Discussion(Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.MRLProposal.Discussion
	Provide any additional information related to the MRL proposal(s), e.g., cases were MRL proposal are based on results from other crops.	Rich text area	FLEXIBLE_SUMMARY.MRLProposal.Discussion.Discussion
Attached background material	Upload any additional material to support the residue definition proposal. Copy this block of fields for attaching more than one file.		FLEXIBLE_SUMMARY.MRLProposal.Discussion.AttachedBackgroundMaterial
Attached document		Single file attachment	FLEXIBLE_SUMMARY.MRLProposal.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	FLEXIBLE_SUMMARY.MRLProposal.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A sanitised version of the attachment/s must be provided for publication. In support of the MRLs proposed for plant commodities, please attach here the OECD calculator Excel	Attachments list	FLEXIBLE_SUMMARY.MRLProposal.Discussion.AttachedSanitisedDocsForPublication

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	<p>file, available on https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm, including the residue values used to derive the MRL proposal(s). The MRLs proposed for animal commodities, should be justified by the Animal Calculator Excel, which is uploaded in the endpoint summary of Section 6.4 (Feeding studies). The uploaded file should not contain confidential material.</p>		
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6.9 Estimation of the potential and actual exposure through diet and other sources – Flexible summary

Purpose:

To provide an overview of the estimated potential or actual exposure to the active substance/metabolite(s) to humans through the intake of food and other means from the uses under consideration (e.g. representative/intended GAP and/or MRLs) and highlighting whether a risk for consumer is expected. In the long-term (chronic) risk assessment, the estimated chronic dietary exposure is compared with the acceptable daily intake (ADI) value which gives the concentration of a chemical that can be consumed over a long period without unacceptable negative health effects. For the short-term (acute) risk assessment, the Acute Reference Dose (ARfD) is used to identify possible consumer health risks. The ARfD gives the concentration of a chemical that can be ingested over a short period of time (one meal, one day) without appreciable risks. EFSA PRIMo (Pesticide Residue Intake Model), an Excel-based calculation spreadsheet, is the standard tool used at EU level to perform the dietary risk assessment for pesticide residues in the framework of setting and reviewing of maximum residue levels for pesticides under Regulation(EC) No 396/2005 and in the peer review of pesticides under Regulation (EU) No 1107/2009. EFSA guidance on the Use of EFSA PRIMo rev 3, available <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5147>.

FLEXIBLE_SUMMARY.ExpectedExposure v.1.1 (Final)

Name	Instructions	Type	Field path
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Administrative data		Header 1	FLEXIBLE_SUMMARY.ExpectedExposure.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.ExpectedExposure.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation
	<p>Optional text box to specify any particular issue related to the exposure assessment that could not be reported in the following tables. Make reference to the risk assessment residue definition reported in the Proposed residue definitions document, the toxicological reference values reported in the Toxicological reference values document and Processing/peeling factors reporting in the Nature and magnitude of residues in processed commodities document.</p> <p>When estimating the exposure it shall be born in mind that the risk assessment has to take into account the residue definition established for risk assessment.</p> <p>Describe if relevant, the possible presence of pesticide residues</p>	Rich text area	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.KeyInformation

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	<p>arising from sources other than current plant protection uses of active substances (for example use of active substances resulting in common metabolites, use as biocide or veterinary drug), and how their aggregate exposure shall be taken into account.</p> <p>Describe the method and results, if cumulative exposure to more than one active substance has been performed.</p>		
Exposure from dietary sources		Header 2	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources
	<p>Please summarize in the table the key results of the consumer exposure assessment by PRIMo, indicating the uses under consideration (e.g. representatives and/or MRLs) and highlighting whether a risk for consumer is expected.</p> <p>-Highest Theoretical Maximum Daily Intake (TMDI): % of ADI, diet and highest contributing commodities -Highest International Estimated Short-Term Intake (IESTI) *: % of ARfD, highest</p>	Rich text area	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.field3689

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	<p>contributing commodities, consumer group</p> <p>-Highest IESTI New**: % of ARfD, highest contributing commodities, consumer group, threshold value (in case IESTI New >100% ARfD)</p> <p>* Scenario 1 should reflect the currently used EU risk assessment methodology using variability factors agreed by EU risk managers and the highest residue (HR) or the Supervised Trials Median Residue (STMR) according to case 1, 2a/2b and case 3 as defined in the FAO Manual (FAO, 2016, available in http://www.fao.org/3/i5452e/i5452e.pdf)</p> <p>** scenario 2, the acute exposure should be calculated in line with the recommendations of the international workshop on revisiting the IESTI equations (see EFSA guidance on the Use of EFSA PRIMo rev 3, available https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5147)</p>		
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	<p>Please use the recommended formats, available on knowledge junction ([cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.9]. Please repeat the tables as much as necessary.</p>		
Exposure from other sources (drinking water)		Header 2	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureOtherSources
	<p>Exposure from other sources (drinking water).</p> <p>Please report in the Table the additional contribution to consumer intake through drinking water resulting from groundwater metabolites expected to be present above 0.75 µg/L. Indicate any metabolites included in the exposure assessment. Report PECgw or make reference to the information reported in Estimation of concentrations in ground water. Please use the recommended formats, available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.9]. Please</p>	Rich text area	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureOtherSources.field4124

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	repeat the tables as much as necessary.		
Additional information		Header 1	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion
	<p>Provide any additional information, this can be in the format of tables. Indicate any deviations applied in the exposure calculation (changes in consumption data, variability factors, etc.).</p> <p>If conversion factors (CF) from enforcement to risk assessment applied, please specify to which commodities/commodity groups. Indicate whether various scenarios of the dietary exposure were calculated. Summarise assumptions for input values. Indicate risk mitigation measures applied.</p>	Rich text area	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion.Discussion
Attached background material			FLEXIBLE_SUMMARY.ExpectedExposure.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			

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<p>Attached (sanitised) documents for publication</p>	<p>A sanitised version of the attachment/s must be provided for publication. Please upload here the PRIMo calculation. In case different scenarios are assessed, please repeat the block as much as necessary and explain the different scenarios in the remark field. An empty template of the PRIMo file is available on `knowledge junction (Residue Template 6.6: PRIMo rev.3.: http://doi.org/10.5281/zenodo.1137758)`. The uploaded file should not contain confidential material.</p>	<p>Attachments list</p>	<p>FLEXIBLE_SUMMARY.ExpectedExposure.Discussion.AttachedSanitisedDocsForPublication</p>
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6.9 Estimation of the potential and actual exposure through diet and other sources – Endpoint study record

Purpose:

This endpoint study record is not relevant and should not be used. Conclusions on the dietary exposure calculations, including the methodology applied, deviations considered and any attachments (e.g. PRIMo.xls), should be reported in the ENDPOINT SUMMARY of section 6.9.

6.10 Other studies - Endpoint summary

ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs v.6.3 (Final)			
Name	Instructions	Type	Field path

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Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.LinkToRelevantStudyRecord.Link
Description of key information		Header 1	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.KeyInformation
		Rich text area	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.KeyInformation.KeyInformation
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion
	Provide a brief description of additional study(ies) and of the key conclusions derived from this/these study(ies).	Rich text area	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion. Discussion
Attached background material	Provide the original version of any additional useful document that contains confidential material		ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion.

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			AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion. AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion. AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Provide any document for publication	Attachments list	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion. AttachedSanitisedDocsForPublication

6.10 Other studies – Endpoint study record

Purpose:

Use this section to report any study that does not fit into other specific endpoints study records or endpoints study summaries of the Section 6 (e.g. specific studies used to refine the consumer risk assessment such studies on variability factors).

ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood v.6.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.DataProtection

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Endpoint	Select from picklist 'additional information on residue chemistry'	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.RationalReliability

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Data waiving		Closed list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference.ReasonPurpose

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Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource
Reference		Literature reference list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods
Background information		Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.BackgroundInformation
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible	Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.ProductType

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	resistance). This field is optional.		
Test guideline			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.GLPComplianceStatement

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Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Study design		Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.StudyDesign
Details on study design		Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.StudyDesign.FurtherDetailsOnStudyDesign

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<p>Any other information on materials and methods incl. tables</p>	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	<p>Header 2</p>	<p>ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables</p>
		<p>Rich text area</p>	<p>ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation</p>

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Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicationSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicationSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached.	Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicationSummaryAndConclusion.ExecutiveSummary

6.10.1 Effect on the residue level in pollen and bee products – Endpoint summary

Purpose:

provide a summary overview on the transfer of residues into pollen and bee products when active substance is applied on melliferous crop according to the intended/critical use pattern and whether any adverse risk to bee health was observed in the context of the present dossier.

Please report the key results on the residue levels in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

ENDPOINT_SUMMARY.SupplementaryStudies v.1.1 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.SupplementaryStudies.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.SupplementaryStudies.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.SupplementaryStudies.LinkToRelevantStudyRecord
Study name / type	Provide here the link to the most relevant study(ies) from which the key values for	Endpoint reference list	ENDPOINT_SUMMARY.SupplementaryStudies.LinkToRelevantStudyRecord.Link

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	magnitude of residues in honey and setting of MRLs in honey are derived.		
Results		Read-only	ENDPOINT_SUMMARY. SupplementaryStudies. LinkToRelevantStudyRecord.Results
Description of key information		Header 1	ENDPOINT_SUMMARY. SupplementaryStudies. KeyInformation
	Please make a statement whether the magnitude residues in bee products was sufficiently investigated (according the current data requirements and to the latest version of the Technical Guideline SANTE/11956/2016) in the context of the present dossier and highlight data gap(s) and the non-standard uncertainty(ies), if any. Please report here the type of the experimental study according to the latest version of the Technical Guideline SANTE/11956/2016 (e.g., experimental studies via syrup feeding, field residue trials or tunnel trials), which was designed with an objective to determine the inadvertent residue in honey arising from pesticide use, in order to allow a dietary risk assessment and to	Rich text area	ENDPOINT_SUMMARY. SupplementaryStudies. KeyInformation.KeyInformation

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	<p>establish scientifically-based MRLs.</p> <p>The relevance of results should be discussed in relation to the proposed uses of the plant protection product, including a critical appraisal of the study and its results. In particular the following points must be addressed:</p> <ul style="list-style-type: none"> - A residue at or above the LOQ (a value of 0.05 mg/kg or lower is favoured) in control samples - Adverse effects on health of the honeybees - MRL proposal and risk assessment values <p>If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here.</p>		
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. SupplementaryStudies. Discussion
	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY. SupplementaryStudies. Discussion.Discussion
Attached background material	Add any additional document that support the above key results		ENDPOINT_SUMMARY. SupplementaryStudies.

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	(e.g. calculation tables, graphs).		Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY. SupplementaryStudies. Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY. SupplementaryStudies. Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs).	Attachments list	ENDPOINT_SUMMARY. SupplementaryStudies. Discussion.AttachedSanitisedDocsForPublication

6.10.1 Effect on the residue level in pollen and bee products – Endpoint study record

Purpose:

Studies to determine the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities v.1.4 (Final)

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist: - residues in honey - residues in pollen	Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.Endpoint

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	<ul style="list-style-type: none"> - residues in other bee products <p>Once selected the endpoint, in the Remark field indicate the type of experimental study, according to the latest version of the Technical Guideline SANTE/11956/2016, i.e.,</p> <ul style="list-style-type: none"> - Experimental study via syrup feeding - Experimental field data - Experimental tunnel data 		
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.StudyPeriod

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Reliability		Open list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.Adminis

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			trativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.DataSource
Reference	Literature reference v.5.1 (Final)	Literature reference list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods
Test guideline	Indicate according to which test guideline the study was conducted. (There are two options referring to the same guideline "Residue		ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline

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	<p>Levels in honey SANTE/11956/2016 rev. 9” and “Technical Guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residues Levels in honey”. If the study was performed according to this guideline, by convention please select “Residue Levels in honey SANTE/11956/2016 rev. 9”).</p> <p>If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'. Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline).</p>		
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.Material

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			sAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study	Please describe here any information relevant to a specific experimental study not mentioned elsewhere as required according to the latest version of the Technical Guideline SANTE/11956/2016. You can report data according to two options: Option 1: use the free text to describe specific experimental study, or	Text template	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy

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	<p>Option 2: to report data in a table format to be inserted in the section ` Any other information on materials and methods incl. tables`, ensuring that the following information is reported: For the experimental study via syrup feeding please provide the information on the formulation type, the content of a.s. in feeding solution [g/L], water solubility, LogPow, photolytic degradation, content of sugar in feeding solution [g/L], application method and test duration, incl. period prior to feeding. Information on the matrix used (feeding solution), sampling method, dates of sampling, number of replicates, sugar content in nectar/honey (% BRIX), water content in nectar/honey (%), days from start of feeding until honey shall also be reported. For the experimental study field test /tunnel test ("semi-field test") please provide information on the number of bee colonies (for tunnel trials), number of bee hives (for field trials), health effects on honeybees,</p>		
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	<p>formulation type, content of active substance in the formulation, water solubility, LogPow, photolytic degradation, the crop/variety, date of flowering, date of application, site parameters, including crops growing in the surroundings, method of application, application details and rate per treatment (kg a.s./ha), weather data for the application, growth rate of the crop (BBCH stage), species tested, duration of bee's exposure (days). Information on the matrix (e.g. plant, flower), sampling date, sampling method, days after last treatment (DALA), growth stage of crop (e.g. BBCH) at sampling, sugar content in nectar/honey (% BRIX), water content in nectar/honey (%) shall be also reported here. Additionally, please provide information related to sampling (sample material, weight, periods of drying, sugar content (%)), and storage of field samples (duration, temperature, storage conditions, honey conditioning, etc.</p>		
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	<p>For details of the analytical method validation data, please make a reference to Section 4 of the dossier `Analytical methods` and leave this field empty. Reference to the corresponding endpoint study record (UUID) is sufficient. If the method has not been reported in Section 4 of the dossier, include table with validation data in the field `Any other information on materials and methods incl. tables`).</p>		
<p>Specific details on test material used for the study (confidential)</p>		Text template	<p>ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential</p>
<p>Any other information on materials and methods incl. tables</p>	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a</p>	Header 2	<p>ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables</p>

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	<p>word processing or spreadsheet document.</p> <p>If you did not use the option 1 to report the detailed information for each experimental study, please report it here in one/several table(s).</p> <p>For the analytical method validation data: if the method has been reported in Section 4 of the dossier 'Analytical methods', please refer to it, providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and contain the data on method validation, further information is not required. If no study record was created for this method (and its validation) in Section 4 of the dossier, please use recommended format available in knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.5]. Please repeat the tables as much as necessary.</p>		
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.AnyOther

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			InformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ResultsAndDiscussion
Any other information on results incl. tables	<p>Discuss and evaluate the reported measurements and the relevance of results in relation to the proposed uses of the PPP, including a critical appraisal of the study and its results. The results of the study can be also presented in a table format. In particular the following points must be addressed:</p> <ul style="list-style-type: none"> - a residue at or above the LOQ (a value of 0.05 mg/kg or lower is favoured) in control samples. - MRL proposal, with reasoning, and derived risk assessment values. 	Header 2	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicantSummaryAndConclusion

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Key result		Read-only	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicationSummaryAndConclusion.KeyResult
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicationSummaryAndConclusion.Conclusions
Executive summary	<p>Briefly summarise the relevant aspects of the study including the conclusions reached. In case new compounds have been identified in bee product, which are not included in the risk assessment residue definition in plant commodities please report this information here. Example:</p> <p>In case of field test/tunnel test: The residue trials for the determination of residues of [test substance] in [bee product] from [name crop] were conducted in [country, location] during the [year] growing season. [Active ingredient, % ai, formulation type] was applied to [crop] at [rate of application (xx g ai/ha)] under [specify trial conditions (field/tunnel)].</p> <p>In case of syrup feeding study: [residue of concern] was administered via syrup</p>	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicationSummaryAndConclusion.ExecutiveSummary

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	<p>[application method] to bees for [duration] consecutive days. Dosing was made at [list dosing levels in mg/kg feed].</p> <p>[Bee product] samples were collected at [conditions of sampled product (maturity, water content (%) etc.)] at [crop growth stage].</p> <p>Residues of [active substance/metabolites] were present at the level of [xx] mg/kg in control samples of [bee product]/not present in control samples of [bee product] above the LOQ of [xx] mg/kg in control samples.</p> <p>In [bee product] the residues of [active substance/metabolites] were present at the level of [xx] mg/kg.</p> <p>All samples were frozen at the testing facility and remained frozen during shipping and storage prior to processing and analysis. The maximum storage interval for samples was [xx] days/months [specify period from harvest to processing and from processing to analysis]. Storage conditions and durations are supported</p>		
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	<p>by studies showing that residues of [active ingredient] are stable in [crops/processed commodities] for up to [xx] days under frozen conditions.</p> <p>Samples in the current study were analyzed using Method [Method ID], a [describe method] method to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] mg/kg per analyte for [matrices].</p>		
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6.11 Migration of residues into and their behaviour on food or feeding stuffs - Endpoint Summary

Purpose

This section is inherited from OHT 85-1 but is not requested in the context of an active substance application, provided that the specific sections 6.1 to 6.10 allows to report all the data supporting the application. It is highlighted that all relevant data on the nature and magnitude of residues in food or feeding stuffs should be reported in the respective sections (6.2, 6.3, 6.4, 6.5) but not here.

ENDPOINT_SUMMARY.MigrationOfResiduesIntoAndTheirBehaviourOnFoodOrFeedingstuffs v.3.0

Name	Instructions	Data type	Field path

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Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MigrationOfResiduesIntoAndTheirBehaviourOnFoodOrFeedingstuffs.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.MigrationOfResiduesIntoAndTheirBehaviourOnFoodOrFeedingstuffs.Discussion

6.11 Migration of residues into and their behaviour on food or feeding stuffs- Endpoint study record

<p>Purpose</p> <p>The purpose of this section is reporting studies concerning the persistence and likelihood of multiplication of viable residues or the production of non-viable residues in or on treated articles, feedingstuffs or foodstuffs following treatment under good agricultural conditions relevant for the representative use(s).</p> <p>A substantiated estimation of persistence/competitiveness (likelihood of multiplication) of the micro-organism and of the persistence and likelihood of production of secondary metabolites/toxins in or on the crop under the environmental conditions prevailing at and after the intended/authorised/representative use, taking into account in particular the information provided in Section 2 on its biological properties however as well on its toxicological properties, has to be delivered.</p> <p>Moreover, the application shall state to which extent and on which basis it is considered that the micro-organism can (or cannot) multiply in or on the plant or plant product or during processing of raw products.</p>

ENDPOINT_STUDY_RECORD.MigrationOfResidues v.6.3			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MigrationOfResidues.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MigrationOfResidues.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.MigrationOfResidues.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.MigrationOfResidues.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.MigrationOfResid

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			ues.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.MigrationOfResidues.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.MigrationOfResidues.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion
Migration into food or feedingstuffs	Provide detailed results of the persistence and likelihood of production and/or multiplication in or on treated articles, feedingstuffs or foodstuffs of <u>non-viable and/or viable residues</u> post application following good agricultural practices.		ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.MigrationIntoFoodOrFeedingstuffs
Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Closed list	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.MigrationIntoFoodOrFeedingstuffs.TestNo
Test conditions	Briefly specify the relevant test conditions, e.g. contact time, concentration of substance and the limit of detection.	Text	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.MigrationIntoFoodOrFeedingstuffs.TestConditions
Observation	Select the qualitative description (e.g. 'distinct migration') that characterises the observed migration of test substance into the food or feedingstuffs	Open list with remarks	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.MigrationIntoFoodOrFeedingstuffs.Observation

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	<p>examined. As appropriate, include quantitative data and/or any explanations in the supplementary remarks field. The phrase 'not determined' may be used if migration was not measured in a test run. The reason should be explained in the supplementary remarks field.</p> <p>For more detailed information or tables use fields 'Details on results' or 'Any other information on results incl. tables', respectively.</p> <p>For microorganisms indicate whether the micro-organism and relevant secondary metabolites (especially toxins) were persistent in the feeding stuff</p>		
Transformation products	<p>Please indicate available information, on any transformation products e.g. of metabolites.</p> <p>Provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	<p>Indicate, if available, the identity of the transformation products. Copy this block of fields for each</p>		ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.IdentityTransformation

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	<p>relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.</p>		
No.	<p>For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.</p>	Closed list	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	<p>Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.</p>	Entity reference field	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Indication of organoleptic changes	<p>Indicate whether any organoleptic changes in food, feedingstuffs or drinking water were observed or not. In below field 'Details on results', give details or provide any further explanation as appropriate. Select 'not examined' or 'not specified' as applicable. This field is optional.</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.IndicationOfOrganolepticChanges

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<p>Details on results</p>	<p>Briefly summarise all relevant results on the migration of the substance and/or behaviour of the residues including any transformation products on food or feedingstuffs, in addition to the information entered in distinct fields. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>As appropriate also attach figures with kinetics of disappearance curves in field 'Illustration (picture/graph)' in 'Overall remarks, attachments'.</p> <p>Note: Specific tables may be required. Consult the programme-specific guidance thereof.</p> <p>For microorganisms provide information on observations of germination, infection, invasion of virulence.</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.DetailsOnResults</p>
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Any other information on results incl. tables	Any other information on results incl. tables Block Provide raw data in tabulated format	Header 2	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.MigrationOfResidues.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block Conclusion: Include a concise conclusion on <u>the anticipated persistence and likelihood of production and multiplication of non-viable and/or viable residues in or on treated articles, feedingstuffs or foodstuffs post application following good agricultural practices</u>	Header 1	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ApplicantSummaryAndConclusion

7. Fate and behaviour in the environment

Purpose:

Provide summary information of the most relevant study(-ies) from which the key value for assessment is extrapolated. Provide only the most relevant details related to:

Mobility

Microorganisms: Persistence and multiplication (competitiveness) in soil, water and air

Chemicals: Fate and behaviour in soil, water and air

This document can be used to summarise information from a range of different studies to conclude on specific aspects of fate and behaviour or persistence and multiplication in the environment

This document can be used to provide an overarching discussion of the data and how it was handled for the purposes of establishing endpoints.

ENDPOINT_SUMMARY.EnvironmentalFateAndPathways v.5.0 (Final)

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Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block Description of key information: Enter a short description of the most relevant endpoint data. The short description could include for example: -the test guideline used, -the test organism, -the exposure duration, -the contextual information of the origin of the value, -qualitative characterisation of some properties	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.Discussion

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7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies)-Endpoint Summary

Purpose:

These experiments are performed to determine the route and the rate of transformation of the test substance in soil, and to determine the nature and rates of formation of transformation products.

Principle of the study:

- The microbial biomass of soils used for laboratory degradation studies shall be determined immediately before the commencement and at the end of the study.
- The soils used for degradation studies shall be representative of the range of agricultural soils typical of the various regions of the Union where use exists or is anticipated.
- The soils shall fulfil the following conditions: they shall cover a range of organic carbon content, particle size distribution and where on the basis of other information, degradation is expected to be pH dependent, they shall cover approximately the following pH (preferably measured in CaCl₂) ranges: 5 to 6, 6 to 7 and 7 to 8.
- Soils used shall, wherever possible, be freshly sampled. If use of stored soils is unavoidable, storage shall be carried out for a limited time (at the most three months) under defined and reported conditions, which are adequate to maintain soil microbial viability. Soils stored for longer periods of time may only be used for adsorption/desorption studies.
- A soil having extreme characteristics with respect to parameters such as particle size distribution, organic carbon content and pH shall not be used.

ENDPOINT_STUDY_RECORD.BiodegradationInSoil – v6.4 (Final) [October 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Microbial Pesticide Test Guidelines OPPTS 885.5200 Expression in a Terrestrial Environment	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods
Test type	Indicate whether the study was a field trial or laboratory study.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestType

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Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Close list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign
Oxygen conditions	Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.OxygenConditions
Soil classification	Select as cited in the study report. If not available from picklist, select 'other:' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilClassification
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field 'Report date'.	Integer	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.Year
Soil properties	Repeat this block of fields for each different soil used as indicated by the Soil No. Enter soil type as cited in the study report and the respective soil properties.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties
Soil no.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.SoilNo
Soil type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDes

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			ign.SoilProperties.Soi lType
% Clay	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Cla y
% Silt	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Silt
% Sand	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Sa nd
% Org. C	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Or gC
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Ph
CEC	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.CE C
Bulk density (g/cm³)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.SoilProperties.Bul kDensityGcm
% Moisture content	Moisture content of the soil (at pF 2 or at Maximum Water Holding Capacity). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier	Range (Deci mal)	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes

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	is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		ign.SoilProperties.MoistureContent
Soil properties			
Details on soil characteristics	For each soil type, specify soil collection and storage and properties of the soil as far as not indicated in the defined fields. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSoilCharacteristics
Duration of test (contact time)	Specify duration of test in terms of contact time. Repeat block for each soil type. If different test runs have different durations, enter lower and upper value in respective subfields.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime.SoilNo
Duration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime.Duration
Duration of test (contact time)			
Initial test substance concentration	Specify the initial test concentration applied. If different concentrations were used in different test runs, copy this block of fields accordingly. If a range of concentrations is reported, include the lower and upper values in the numeric range field. If appropriate copy this block of fields for indicating different parameters the initial concentration is based on (e.g. COD and test substance).		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDes

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			ign.InitialTestSubstanceConcentration.SoilNo
Initial conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.InitialConc
Based on	From drop-down list, select the parameter on which the initial concentration is based.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.BasedOn
Initial test substance concentration			
Parameter followed for biodegradation estimation	Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as appropriate. In supplementary remarks field, give relevant details on the method. For radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ParameterFollowed
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products and/or non-extractable residues.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods
Experimental conditions	For each soil type, indicate the environmental conditions during the test if available or assumed in the model, if estimated.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close list	ENDPOINT_STUDY_RECORD.Biodegrada

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			tionInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.SoilNo
Temp.	Specify test temperature including mean and range values during test if available or temperature assumed in the model, if estimated. Use °C; convert other units and indicate original data in parentheses if applicable.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.Temp
Humidity	Indicate soil humidity in % moisture content or g water/100g soil dry weight.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.Humidity
Microbial biomass	Indicate initial and final microbial biomass / microbial population of control and treated soil, if provided. Specify unit, e.g., mg biomass/100 g soil dry weight or µg C/g soil.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.MicrobialBiomass
Experimental conditions			
Details on experimental conditions	Include Soil No. in parentheses if conditions were not identical for all soil types tested. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnExperimentalConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion

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Material (mass) balance	If applicable, indicate mean total recovery of test material as percentage of applied amount +/- standard deviation. Copy this block of fields for each soil type as appropriate.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.SoilNo
Sampling date	Enter the date the sample was taken	Date	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.SamplingDate
% Total extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.TotalExtractable
% Non extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.NonExtractable
% CO2	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.CO2
% Other volatiles	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.OtherVolatiles
% Recovery	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.Recovery
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.Biodegrada

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			tionInSoil.ResultsAnd Discussion.MaterialMassBalance.StDev
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.MaterialMassBalance.RemarksOnResults
Material (mass) balance			
% Degradation	For each soil type, indicate percentage of degradation of test substance including standard deviation at the end of the study period. Also indicate on what parameter the degradation rate is based on (e.g. 'radiochemical measurement'). If required, copy block of fields to include values based on different parameters.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation
Parent/product	Indicate if the result reported is for the active substance/parent or the product/metabolite. The identify of the substance can be selected below	Close list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.ParentProduct
Name or code for product	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.NameOrCodeForProduct
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.SoilNo
Sampling date	Enter date when the sample was taken	Date	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd Discussion.Degradation.SamplingDate

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% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.Degr
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.StDev
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.Parameter
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SamplingTime
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Half-life / dissipation time of parent compound	For each soil type, include value (or range if reported so) of half-life and indicate the type of half-life (For first order kinetics DT50 = half-life).		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOf

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			ParentCompound.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.SoiINo
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.HalfLife
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.StDev
Type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.Type
Temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.Temp
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.RemarksOnResults
Half-life / dissipation time of parent			

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compound			
Transformation products	<p>Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.</p> <p>Not relevant for microorganisms</p>	Close list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	<p>Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance.</p> <p>Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.</p>		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation
No.	<p>For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.</p>	Close list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	<p>Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.</p>	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on transformation products	<p>Indicate any relevant supplementary information on transformation products. Use freetext template and delete/add items as appropriate. If useful attach a figure in the corresponding field.</p>	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.TransfProductsDetails
Evaporation of parent compound	<p>Indicate whether evaporation of the parent compound occurred or not. Include any explanations in field 'Details on results' as appropriate.</p> <p>'Yes' should be selected when CO₂ has been detected in volatile traps.</p>	Close list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.EvaporationOfParentCompound

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Volatile metabolites	Indicate whether volatile metabolites were found or not. Include any explanations in field 'Details on results' as appropriate.	Close d list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.VolatileMetabolites
Residues	Indicate whether residues were found or not. Include any explanations in field 'Details on results' as appropriate.	Close d list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Residues
Details on results	<p>Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>In field 'Attached background material', attach graph(s) with the full degradation or elimination curves.</p> <p>TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.</p> <p>MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table.</p> <p>STERILE TREATMENTS: If used, report the transformation of the parent, and compare the results with those of the non-sterile treatments:</p> <p>SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.</p>	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.DetailsOnResults
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.ResultsWithReferenceSubstance
Any other information on	<p>Any other information on results incl. tables Block</p> <p>For Microorganisms the tables in the results and discussion section do not need to reported unless suitable data is available. However Tabulation/graphs of</p>	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.AnyOther

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results incl. tables	population dynamics and Discussion of test results should be provided in this field.		InformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.OverallRemarksAttachments
Kinetic evaluation	The filled "Template 7.1 - template for presentation of kinetic fitting" (https://doi.org/10.5281/zenodo.4557253) shall be uploaded here to report the the visual and statistical kinetic evaluation.	Attachments list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.OverallRemarksAttachments.KineticEvaluation
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ApplicantSummaryAndConclusion

7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies) - Endpoint Summary

Purpose:

Summarise the results of the laboratory studies on the rate of degradation in soil reporting all relevant information on the properties of the soils, the rates of degradation for persistence and modelling for active substance and its metabolites, and the correspondent kinetic models used.

ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP - v.1.3 (Final) [October 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Report Information to support the persistence /rate of degradation in soil. Make reference to the studies used to conclude on the rate of degradation in soil.	Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.AdministrativeDataSummary

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	Multiple endpoint summaries can be created where different DegT50 values are defined at different pH values. The pH should be specified in the 'Description of key information field.		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa
Persistence / rate of degradation in soil			ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.Substance
Test conditions	Provide information on the test conditions, aerobic or anaerobic	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.TestConditions
Soil type	Enter the type of soil used in the laboratory test system.	Text	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.SoilType
pH	Enter the pH value of the soil in the laboratory test system.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the soil pH was measured.	Multi-line text	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistanceDegradationSoil.MeasuredIn

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Soil moisture (%)	Enter the soil moisture at which the incubation was carried out (e.g.: maximum water holding capacity (%) or pF2 (%) or pF2.5 (%) values).	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .SoilMoisture
Half-life in soil (DT50)	Enter the DT50 value for persistence.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .HalfLifeSoil
DT90 in soil	Enter the DT90 value for persistence.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .DtNinetySoil
at the temperature of	Enter the temperature of the soil in the laboratory test system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .Temperature
Chi-square (χ^2)	Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for persistence.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Per sistenceDegradationSoil .KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_E

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	transformation products.		U_PPP.KeyValueCsa.PersistanceDegradationSoil.KineticFormationFracti on
Precursor	For metabolites, when relevant, select the precursor substance (e.g. the active substance or another metabolite).	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.PersistanceDegradationSoil.Precursor
Remarks	Provide any additional information needed to interpret the reported results	Text area	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.PersistanceDegradationSoil.Remarks
Persistence / rate of degradation in soil			
Modelling rate of degradation in soil			ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. Substance
Test conditions	Select the conditions of the study (aerobic/anaerobic).	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. TestConditions
Soil type	Enter the type of soil used in the laboratory test system.	Text	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. SoilType
pH	Enter the pH value of the soil in the laboratory test system.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_E U_PPP.KeyValueCsa.Mo dellingDegradationSoil. Ph

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measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the soil pH was measured.	Multi-line text	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.MeasuredIn
Soil moisture (%)	Enter the soil moisture at which the incubation was carried out (e.g.: maximum water holding capacity (%) or pF2 (%) or pF2.5 (%) values)	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.SoilMoisture
Normalised (DT50)	Enter the DT50 value for modelling at 20°C and pF2/10kPa, normalized using a Q10 of 2.58 and Walker equation coefficient of 0.7.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.NormalisedDtFifty
Chi-square (χ^2)	Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for modelling.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving modelling endpoint (normalised DT50); when biphasic kinetic model is used, it should be specified how the DT50 was derived (DT90 FOMC/3.32, DFOP slow phase, etc...).	Text	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.KineticParameters

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Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.KineticFormationFraction
Precursor	For metabolites, when relevant, select the precursor substance (e.g. the active substance or another metabolite).	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Precursor
Remarks		Text area	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Remarks
Modelling rate of degradation in soil			
Key value for safety assessment			ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.Substance
Half-life in soil (DT50)	Indicate the geometric mean (if not pH dependent) of the normalised DT50 values. If pH dependence is identified, values other than the geometric mean can be reported according to the pH dependency evaluation (please select "yes" in the "pH dependence" field).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.HalfLifeSoil

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Mean formation fraction	Indicate the arithmetic mean of the formation fraction (f.f. kf/kdp) values for the metabolite.	Decimal	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.FormationFraction
pH dependence	Select 'yes' or 'no' to indicate whether the result is pH dependent	Closed list	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.PhDependence
Remarks		Text area	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.Remarks
Key value for safety assessment			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. BiodegradationInSoil_EU_PPP.Discussion

7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies) - Endpoint study record

Purpose:

Summarise the results of studies on the aerobic and anaerobic route of degradation in soil and identify the metabolites requiring further consideration for risk assessment.

ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP – v.1.3 (Final) [October 2020]

Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and metabolites that should be considered for risk assessment	Header 1	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa
Route of degradation in soil	The route of degradation consists in:		ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP.

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	1) determining the amount mineralization; 2) determining the amount of non-extractable residues; 3) identifying metabolites above the regulatory trigger.		KeyValueCsa.Degradati onSoil
Parent / metabolite	Rows should be created for the active substance and each metabolite	Closed list	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.Substance
Test conditions	Indicate whether the results are for aerobic conditions, anaerobic conditions. A summary can be completed for each type of test condition.	Closed list	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.TestConditions
Sterile conditions	Indicate if the results were obtained under sterile conditions	Check box	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.SterileConditions
Mineralisation (%)	Indicate the mineralization percentage after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.Mineralisation
Non extractable residues (%)	Indicate the non-extractable residues percentage after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.MaximumOccurrence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati

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			onSoil.DayMaximumOccurrence
Actual duration (days)	Report the duration of the study in days.	Integer	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.ActualDuration
Radio label	Provide information on the radio labelling used to obtain these results	Text	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.RadioLabel
Number soils	Report the number of soil analysed to obtain these results	Integer	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.NumberSoils
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.Remarks
Route of degradation in soil			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.Discussion

Links to support material:

DG SANCO Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides" (25.09.2012 – rev. 3)

ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment (revision 1)

7.1.2.1 Route of degradation in soil (soil photolysis) – Endpoint summary

Purpose:

Summarise the results of the route and rate of degradation in soil photolysis studies (DegT50) and identify the metabolites requiring further consideration for risk assessment.

Provide only the most relevant details related to the viability/population dynamics in soil and persistence in the terrestrial environment.

Provide only the most relevant details, which could be:

- amounts of test substance given as % of applied initial amount, and as mg·kg⁻¹ soil
- transformation half-life or DT50 and DT90
- if available, any transformation product / metabolite(identity and concentration)
- details on test soil

The document should contain the information needed to be reported according to the list of end points for degradation in soil (SANCO/12592/2012-rev. 2, 22 March 2019).

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ENDPOINT_SUMMARY.PhototransformationInSoil – v.5.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects. In study name/type the type of soil used in the laboratory test system should be provided	Header 1	ENDPOINT_SUMMARY.PhototransformationInSoil.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.PhototransformationInSoil.KeyValueForChemicalSafetyAssessment
Half-life in soil		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.PhototransformationInSoil.KeyValueForChemicalSafetyAssessment.HalfLifeInSoil
Additional information	Discussion(Header 1) – common block For the DT50 value reported above include information on the conditions e.g. soil type, pH, temperature. The method of calculation should also be described. Table in the format of the List of Endpoints: Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3) is recommended	Header 1	ENDPOINT_SUMMARY.PhototransformationInSoil.Discussion

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7.1.2.1 Route of degradation in soil (soil photolysis) – Endpoint study record

Purpose:

The soil photolysis study determining the route and rate of the active substance and the nature and rates of formation of transformation products shall be provided and the related DegT50 value reported. In case the deposition of the active substance on the soil surface is unlikely to occur (not significant) or in case photolysis is not expected to contribute significantly to the degradation of the active substance in soil, e.g. due to low light absorbance of the active substance, a detailed justification shall be provided instead of a soil photolysis study.

Any major metabolites (or other degradation products that at any sampling time during the studies account for more than 10% of the active substance added) should be identified and their degradation rates should be studied.

The recommended methods given in OECD test guideline 307 are appropriate to almost all chemical substances for which an analytical method with sufficient accuracy and sensitivity is available. The test should not be applied to highly volatile chemicals since they cannot be kept in soil under the experimental conditions of this test.

Any deviation from the guideline method used (and reasons for it) or any other special consideration should be reported.

ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil – v.7.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 307: Aerobic and anaerobic transformation in soil Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014) Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration - Final Report of the Work Group on Degradation Kinetics of FOCUS (Sanco/10058/2005, version 2.0, June 2006)	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods

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	EFSA (2007). Scientific Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32.		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign
Analytical monitoring	Indicate whether test substance was monitored in the test solutions. For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.AnalyticalMonitoring
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarks	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on sampling	Enter details on sampling regime and method. Use freetext template as appropriate.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSampling
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods
Details on soil	Using freetext template give details on the soil used. As an alternative option, attach a document e.g. excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAn

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	Note: If applicable, indicate the title and year of the soil classification system used after the respective prompt, i.e. Canadian System of Soil Classification / DIN 19863 (Deutsche Industrie-Norm) / NF X31-107 (Norme française) / USDA (US Department of Agriculture) / WRB (World Reference Base for Soil Resources) / or other (to be specified).		dMethods.StudyDesign .DetailsOnSoil
Light source	Select light source used.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.LightSource
Light spectrum : wavelength in nm	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.LightSpectrumWavelengthInNm
Relative light intensity	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.RelativeLightIntensity
Details on light source	Enter any relevant details on the light source. Use either of the two freetext templates as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnLightSource
Details on test conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions
Duration of test at given test condition	Indicate the test duration and % moisture, temperature and initial test substance concentration at which test was conducted. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition
Duration	Enter numeric value.	Unit measure with Closed List	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGive

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		(Decimal)	nTestCondition.Duration
% Moisture	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Moisture
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Temp
Initial conc. measured	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.InitialConcMeasured
Duration of test at given test condition			
Reference substance	Indicate if test(s) with a substance with known photolysis was performed. If yes, report the identity of the substance in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.ReferenceSubstance
Dark controls	Indicate if dark, i.e. negative controls were used in parallel studies. Remarks can be included in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DarkControls
Computational methods	Enter details on computational methods used to calculate relevant parameters.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.ComputationalMethods

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Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion
Preliminary study	Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.PreliminaryStudy
Test performance	Report on any unusual observations during test, deviations from test procedure or any other information affecting results.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.TestPerformance
Spectrum of substance	Select spectral parameter from picklist and enter value in the subsequent subfield. Any notes can be included in subfield 'Remarks'. Copy block of fields for each parameter cited in the study report. If the substance absorbs light at wavelengths >295 nm, give the wavelength (lambda value) of maximum absorption at wavelengths >295 nm and the maximum molar absorption (extinction) coefficient (epsilon value). If there is no absorption maximum at >295 nm, give the molar extinction coefficient at 295 nm. An alternative to the above is to attach a file that depicts graphically or in tabular form the complete UV/VIS absorption spectrum (include reference to respective Figure or Table No. in subfield 'Remarks').		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum
Parameter	Select parameter from drop-down list and enter the corresponding value or range with unit (unless dimensionless) in the related text field, together with any explanation if necessary, e.g. on the study group the result refers to. Explanations: AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time);	Open list	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Parameter

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	Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration.		
Value	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Value
Remarks	Enter any remarks related to the recorded value as appropriate.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Remarks
Spectrum of substance			
% Degradation	Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.KeyResult
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.DegradationPercent
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.StDev
Sampling time	Enter numeric value.	Unit measure with Close	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.TimePoint

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		d List (Decimal)	
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Quantum yield (for direct photolysis)	Give the reaction quantum yield of the test substance (values between 0 and 1).	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.QuantumYield
Dissipation half-life of parent compound	Provide the half-life / DT50 or range as appropriate. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.KeyResult
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.HalfLife
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAnd

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			Discussion.Dissipation HalfLife.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.RemarksOnResults
Dissipation half-life of parent compound			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transfor			

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Information on products			
Details on results	<p>Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Explanations on freetext prompts: TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered. HALF-LIFE: Include a table with detailed results for dark and irradiated samples including Regression equation, r^2 and DT90 if available. MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table. Distinguish between dark and irradiated samples; compare the transformation products formed in the dark and irradiated samples, and identify and quantify the products that are formed by phototransformation only. As appropriate attach Figure showing the pathway of phototransformation of the test substance. SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.</p>	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.ResultsDetails
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.ResultsReferenceSubstance
Any other information on results	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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incl. tables			
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ApplicantSummaryAndConclusion

7.1.3 Adsorption and desorption in soil – Endpoint summary

Purpose:

Summarize the results of the adsorption/desorption studies to provide the adsorption coefficients of the active substance and its metabolite in the soil.

ENDPOINT_SUMMARY.AdsorptionDesorption v.6.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects. Reference can also be made to the results of aged sorption studies if available.	Header 1	ENDPOINT_SUMMARY.AdsorptionDesorption.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment
Koc at 20 °C	Report the organic carbon adsorption coefficient (Koc)	Decimal	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.KocAt20Celsius
Other adsorption coefficients	If the value for Koc is missing, provide		ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSaf

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	information on other adsorption coefficients.		etyAssessment.OtherAdsorptionCoefficients
Type	Select additional adsorption coefficients. Other can be used in case of a coefficient value which is not in the list	Open list	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients.Type
Value in L/kg		Decimal	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients.TypeValue
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients.AtTheTemperatureOf
Other adsorption coefficients			
Additional information	<p>Discussion(Header 1) – common block Provide the original version of any document that contains confidential material. A table in the format from the List of Endpoints Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1) is recommended. The OECD 106 Evaluator’s checklist report can be uploaded here.</p>	Header 1	ENDPOINT_SUMMARY.AdsorptionDesorption.Discussion

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Links to support material:

European Commission. Scientific Committee on plants SCP/KOC/002-Final. Opinion of the Scientific Committee on Plants on methods for the determination of the organic carbon adsorption coefficient (Koc) for a plant protection product active substance in the context of Council Directive 91/414/EEC (18 July 2002)[3]

Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)

EFSA (2017). Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326

7.1.3.1 Adsorption and desorption – Endpoint study record

Purpose:

Adsorption/desorption studies give information on the mobility of active substance and its metabolites in soil.

Studies on adsorption and desorption of the active substance shall be provided, except where the nature and manner of use of plant protection products containing the active substance preclude soil contamination such as indoor uses on stored products or brush applied wound healing treatments for trees

ENDPOINT_STUDY_RECORD.AdsorptionDesorption – v.6.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.DataSource
Materials and methods	<p>Material and methods – common block</p> <p>Applicable test guideline: OECD Test Guideline 106: Adsorption - desorption using a batch equilibrium method.</p> <p>Indicate the type of method used regardless of whether it is already specified in the guideline, as this field can be used for query purposes.</p>	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods
Media	<p>Indicate the medium (i.e. soil, sediment or sewage sludge) for which the adsorption (desorption) determination was made.</p> <p>For the HPCL estimation method, select</p>	Open list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.Media

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	'soil/sewage sludge'. For any other, select 'other' and specify.		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign
Test temperature	Indicate test temperature values measured during test. Include range, mean, standard deviation and unit.	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.TestTemperature
HPLC method		Header 3	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.HPLCMethod
Details on study design: HPLC method	For the HPLC method only, enter any details on the study design that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.HPLCMethod.DetailsOnStudyDesignHplcMethod
Batch equilibrium or other method		Header 3	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod
Analytical monitoring	Indicate whether test substance was monitored in the test solutions. For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.AnalyticalMonitoring
Details on sampling	If the amount of test material in the test solutions was monitored, enter details on sampling. Use	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.Stu

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	freetext template as appropriate and delete/add elements as appropriate.		dyDesign.BatchEquilibriumOrOtherMethod.DetailsOnSampling
Details on analytical methods	<p>If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate.</p> <p>Reference Analytical method endpoint study record can be included here</p>	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnAnalyticalMethods
Matrix properties	Repeat this block of fields for each different matrix type used as indicated by the Matrix no. Specify the type of soil, sediment or sludge.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties
Matrix no.	Select a consecutive number from drop-down list if more than one matrix type were used.	Close d list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.MatrixNo
Matrix type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.MatrixType
% Clay	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Clay
% Silt	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Silt
% Sand	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Sand

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% Org. carbon	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.OrgCarbon
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Ph
CEC	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.CEC
Bulk density (g/cm³)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.BulkDensityGCm
Matrix properties			
Details on matrix	Depending on the test system, i.e. water-soil or water-sediment or water-activated sludge simulation system, include details on either the soil, sediment or sludge solids used in the study. Select respective freetext template and delete/add elements as appropriate. As an alternative option, include or attach an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnMatrix
Details on test conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. As appropriate or requested by the regulatory programme include tables in the rich text field 'Any other information on results incl. tables' summarising the study design for the adsorption and desorption phase. Upload predefined table(s) if any or adapt table(s) from study report. Use table	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnTestConditions

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	numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').		
Duration of adsorption equilibration	Indicate sample number (if multiple types of soil/sediment/sludge were used), indicate temperature and initial pH and test substance concentration at which adsorption was conducted and the respective test duration. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used. Create a new row for each sample/soil tested	Close d list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.SampleNo
Duration	Enter numeric value.	Unit measure with Close d List (Deci mal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.Duration
Initial conc. measured	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Rang e with open list (Deci mal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.InitialConcMeasured
pH	Enter the initial pH.	Deci mal	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.Ph
Temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Rang e with close d list (Deci mal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.Temp

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Remarks	Enter any remarks related to the duration of the adsorption equilibration.	Text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.Remarks
Duration of adsorption equilibration			
Duration of desorption equilibration	Indicate sample number (if multiple types of soil/sediment/sludge were used), temperature and amount of test substance concentration in the adsorbed state and the respective test duration. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used. Create a new row for each sample/soil tested	Close list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.SampleNo
Duration	Enter numeric value.	Unit measure with Close List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Duration
Conc. of adsorbed test mat.	Enter a numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.ConcOfAdsorbedTestMat
pH	Enter the initial pH.	Decimal	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.Stu

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			dyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Ph
Temp.	Enter a numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Temp
Remarks	Enter any remarks related to the duration of the adsorption equilibration.	Text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Remarks
Duration of desorption equilibration			
Computational methods	Enter details on computational methods used to calculate relevant parameters. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.ComputationalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion
Adsorption coefficient			ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient

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Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.KeyResult
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Close list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.SampleNo
Type	Either of the following parameters can be selected from the drop-down list: adsorption coefficient Koc or log Koc, distribution constant Kd or log Kd. Include any explanations in the supplementary remarks field as appropriate. For reporting partition coefficients (Kp / log Kp) please use the next block of fields 'Partition coefficients'.	Open list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.Type
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.Value
pH	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.Ph
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.Temp
Matrix	This free text field can be used to specify the matrix tested if several types were used, e.g. 'Soil no. 1: clay', 'sediment type' etc.	Text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.Matrix
% Org. carbon	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.PercentAgeOfOrganicCarbon

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Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.RemarksOnResults
Adsorption coefficient			
Partition coefficient	Include any relevant solids-water partition coefficient Kp or log Kp for the compartment-water system covered (e.g. log Kp solids-water in soil). If required, copy block of fields to include several parameters.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.KeyResult
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Close list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.SampleNo
Phase system	Indicate the compartment-water system or select 'other:' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.PhaseSystem
Type	Select 'Kp' or 'log Kp' from the drop-down list. Include any explanations in the supplementary remarks field as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Type
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Value
Temp.	Enter numeric value.	Unit measure with	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Temp

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		Close d List (Deci mal)	
pH	Enter numeric value.	Deci mal	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionOther.Ph
Matrix	This free text field can be used to specify the matrix tested if several types were used, e.g. 'Soil no. 1: clay', 'sediment type' etc.	Text	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionOther.Matrix
% Org. carbon	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Rang e (Deci mal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionOther.OrgCarbon
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with rema rks (200 0)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionOther.RemarksOnR esults
Partition coefficients			
Results: HPLC method		Head er 2	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Res ultsHplcMethod
Details on results (HPLC method)	For the HPLC method only, include further data as indicated in the freetext template.	Text templ ate	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Res ultsHplcMethod.DetailsOn ResultsHplcMethod
Results: Batch equilibriu m or other method		Head er 2	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Res ultsBatchEquilibriumOrOth erMethod

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Adsorption and desorption constants	<p>For each soil used provide adsorption and desorption constants including data on the slope of Freundlich adsorption/desorption isotherms (1/N) and regression coefficient of Freundlich equation (R2). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.AdsorptionAndDesorptionConstants
Recovery of test material	<p>Indicate recovery of test material in supernatant solution and solid phase as well as non-extractable residues after adsorption/desorption, including mean standard deviation. Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.RecoveryOfTestMaterial
Concentration of test substance at end of adsorption equilibration period	<p>Give concentration of test substance in solid and liquid phases at the end of adsorption equilibration period and percent adsorbed test material of applied, including standard deviation; indicate whether the amount on sorbent residue is measured by sorbent residue analysis or calculated by difference (total applied - concentration in solution). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.ConcentrationOfTestSubstanceAtEndOfAdsorptionEquilibrationPeriod
Concentration of test substance at end of desorption equilibration period	<p>Give concentration of test substance in solid and liquid phases at the end of desorption equilibration period and percent desorbed test material of adsorbed, including standard deviation; indicate whether the amount on sorbent residue is measured by sorbent residue analysis or calculated by difference (total applied - concentration in solution). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.ConcentrationOfTestSubstanceAtEndOfDesorptionEquilibrationPeriod

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Mass balance (%) at end of adsorption phase	Indicate sample number (if multiple types of soil/sediment/sludge were used), duration of end of adsorption phase and include the respective mass balance as % of the applied test substance. For indicating values for different soil (samples), copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Close d list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.SampleNo
Duration	Enter numeric value.	Unit measure with Close d List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.Duration
% Adsorption	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.AdsorptionPercentage
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:', e.g. details on soil.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.RemarksOnResults
Mass balance (%) at end of adsorption phase			
Mass balance (%) at	Indicate sample number (if multiple types of soil/sediment/sludge were used), duration of end of desorption phase and include the respective		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.Res

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end of desorption phase	mass balance as % of the applied test substance. For indicating values for different soil (samples), copy this block of fields as appropriate.		ultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.SampleNo
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.Duration
% Desorption	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.DesorptionPercentage
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:', e.g. details on soil.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.RemarksOnResults
Mass balance (%) at end of desorption phase			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.TransformationProducts

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Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Close d list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on results (Batch equilibrium method)	Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.DetailsOnResultsBatchEquilibriumMethod
Statistics	Indicate the parameters analyzed, the statistical method used and the statistical test performed.	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.Statistics
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit	Rich text area	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.Any

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	any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.		OtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block Kinetic report/s can be uploaded here.	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.OverallRemarksAttachments
Applicants' summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ApplicantSummaryAndConclusion

Links to support material:

European Commission. Scientific Committee on plants SCP/KOC/002-Final. Opinion of the Scientific Committee on Plants on methods for the determination of the organic carbon adsorption coefficient (Koc) for a plant protection product active substance in the context of Council Directive 91/414/EEC (18 July 2002)

Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)

EFSA (2017). Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326

7.1.3.2 Aged sorption – Endpoint study record

Purpose:

As a higher tier option, information on aged sorption may be provided. Time dependent sorption studies should be report in this document

ENDPOINT_STUDY_RECORD.AgedSorption – v.1.2 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.DataSource

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Materials and methods	Material and methods – common block Applicable test guideline: focus groundwater; OECD 307; -- SANTE/12586/2020 – REV 0 26 January 2021 Guidance on how aged sorption studies for pesticides should be conducted, analyzed and used in regulatory assessments.	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods
Type of study	Include only information that does not fit into any of the specific chapters. Indicate the type of information, e.g. 'Soil leaching'. If not available from the picklist, use 'other:' and include an appropriate description. Include any relevant information from a study report or publication in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' or 'Overall remark' as appropriate. Fill in fields for Administrative data and Data source as appropriate.	Open list	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods.TypeOfStudy
Media	Indicate the media addressed.	Open list	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods.Media
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AgedSorption.Ma

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			terialsAndMethods.Test Materials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AgedSorption.Mat erialsAndMethods.Any OtherInformationOnMat erialsAndMethodsInclTa bles
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.Re sultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AgedSorption.Re sultsAndDiscussion.Any OtherInformationOnRes ultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.Ov erallRemarksAttachmen ts
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.Ap plicantSummaryAndCon clusion

7.1.4 Mobility in soil, leaching and lysimeter studies – Endpoint summary

<p>Purpose: Chemicals: conclude on the mobility and leaching potential of the active substance, metabolites, breakdown and reaction products Microorganisms: Provide sufficient data to evaluate the mobility of the micro-organism and its degradation products in relevant environmental compartments.</p> <p>Where studies are provided for more than one endpoint separate summaries can be created for each endpoint.</p>
--

ENDPOINT_SUMMARY.OtherDistributionData – v.3.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.OtherDistributionData.A dministrativeDataSumm ary

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	Provide a brief description of relevant studies and effects.		
Additional information	<p>Discussion (Header 1) – common block</p> <p>Provide additional information related to the endpoint. Presentation of the results in the tabular format of the List of Endpoints Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1) and Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3) is recommended</p> <p>If there is no additional information to be reported this field may be left empty.</p>	Header 1	ENDPOINT_SUMMARY. OtherDistributionData.D iscussion

Links to support material:

Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)

7.1.4 Mobility in soil, leaching and lysimeter studies – Endpoint study records

Purpose:

Chemicals/Microorganisms: Provide sufficient data to evaluate the mobility and leaching potential of metabolites, breakdown and reaction products.

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ENDPOINT_STUDY_RECORD.OtherDistributionData -v.6.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 312: Leaching in Soil Columns.	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods
Type of study	Include only information that does not fit into any of the specific chapters. Indicate the type of information, e.g. 'Soil leaching'. If not available from the picklist, use 'other:' and include an appropriate description. Include any relevant information from a study report or publication in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' or 'Overall remark' as appropriate. Fill in fields for Administrative data and Data source as appropriate.	Open list	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.TypeOfStudy
Media	Indicate the media addressed.	Open list	ENDPOINT_STUDY_RECORD.OtherDistribution

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			Data.MaterialsAndMethods.Media
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.ApplicantSummaryAndConclusion

Links to support material:

OECD Guidance Document 22: Guidance Document for the Performance Of Out-door Monolith Lysimeter Studies <https://doi.org/10.1787/20777876>

7.2 Fate and behaviour in water and sediment

7.2.1 Route and rate of degradation in aquatic systems

7.2.1.1 Hydrolytic degradation - Endpoint summary

Purpose:

Summary information of the most relevant study(ies) from which the key value for environmental fate and chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:

- amounts of test substance given as % of applied initial concentration and given as mg/l
- transformation half-life or DT50 for 20°C or 25°C
- related conditions (temperature, pH)
- Identity of degradation products (if any)

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ENDPOINT_SUMMARY.Hydrolysis v5.0 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block Multiple endpoint summaries can be created where different DegT50 values are defined at different pH values. The pH should be specified in the 'Description of key information field	Header 1	ENDPOINT_SUMMARY.Hydrolysis.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Hydrolysis.KeyValueForChemicalSafetyAssessment
Half-life for hydrolysis		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Hydrolysis.KeyValueForChemicalSafetyAssessment.HalfLifeForHydrolysis
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Hydrolysis.KeyValueForChemicalSafetyAssessment.AtTheTemperatureOf
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Hydrolysis.Discussion

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7.2.1.1 Hydrolytic degradation – Endpoint study record

Purpose:

The hydrolytic degradation rate at different pH values (pH 4, 7 and 9) of purified active substance shall be determined at 20 °C or 25 °C and the half-life or DT50 values reported.

The recommended test method to assess the abiotic hydrolytic transformation of substances in aquatic systems at environmentally relevant pH range (pH 4 – 9) is given in OECD test guideline 111. An appropriate analytical method with sufficient accuracy and sensitivity for the active substance shall be available.

The method is not applicable to highly volatile substances, since the substance cannot be kept in solution under the experimental conditions of this test.

In case of substances of minimal solubility in water the test may be difficult to conduct.

In case of readily biodegradable substances and/or highly insoluble substances, the study does not need to be conducted. A justification of study waiving shall be provided.

In case of predicting the hydrolytic degradation beside the applied approach, all relevant parameter shall be provided.

Studies on hydrolytic degradation shall also be performed for degradation and reaction products which account at any time for more than 10 % of the amount of active substance added in the hydrolysis study, unless sufficient information on their degradation is available from the test performed with the active substance.

ENDPOINT_STUDY_RECORD.Hydrolysis v6.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Hydrolysis.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Hydrolysis.DataSource
Materials and methods	Material and methods – common block Applicable Test guidelines: OECD Test Guideline 111: Hydrolysis as a Function of pH	Header 1	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Hydrolysis.Materials

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	Details on labelled material to be described in field 'Details on test material'.		AndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign
Analytical monitoring	Indicate whether test substance was monitored in the test solutions. For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.AnalyticalMonitoring
Details on sampling	Enter details on sampling regime and method. Use freetext template as appropriate.	Text template	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.DetailsOnSampling
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information	Text template	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods

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	for transformation products.		
Buffers	Give details on the buffer(s) used for each nominal pH tested; copy any subheading(s) as appropriate for indicating buffers at different pH values. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.Buffers
Estimation method (if used)	If an estimation method was used, describe relevant details and input parameters and/or indicate the computer programme used.	Text area	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.EstimationMethodIfUsed
Details on test conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions
Duration of test	Indicate the test duration, pH and temperature condition and initial test substance concentration at which test was conducted. Copy this block of fields for different test conditions as appropriate.		ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.DurationOfTest
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Hydrolysis.Materials

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			AndMethods.StudyDesign.DurationOfTest.Duration
pH	Enter the pH value during the test.	Decimal	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.DurationOfTest.Ph
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.DurationOfTest.Temp
Initial conc. measured	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.DurationOfTest.InitialConcMeasured
Remarks	Enter any remarks related to test duration.	Text	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.DurationOfTest.Remarks
Duration of test			
Number of replicates	Indicate the number of replicates tested. If different at the different test runs, specify for each pH and temperature.	Multi-line text	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.NumberOfReplicates
Positive controls	Indicate if a positive control (test with a substance with known hydrolysis) was performed. If yes, report the identity of the substance in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.PositiveControls

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Negative controls	Indicate if a negative control (test with a stable substance) was performed. If yes, report the identity of the substance in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.NegativeControls
Statistical methods	Enter details on statistical methods used to interpret the results.	Multi-line text	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.StudyDesign.StatisticalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Hydrolysis.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion
Preliminary study	Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.PreliminaryStudy
Test performance	Report on any unusual observations during test, deviations from test procedure or any other information affecting results.	Multi-line text	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.TestPerformance
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.TransformationProducts

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Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on hydrolysis and appearance of	Indicate the hydrolysis of the test	Text template	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsA

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<p>transformation product(s)</p>	<p>material and appearance of transformation products, expressed as percentage of the parent substance or applied radioactivity. Use freetext template and delete/add items as appropriate. Particularly with comprehensive data include a table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). If useful attach a figure in field 'Attached background material'.</p>		<p>ndDiscussion.DetailsOnHydrolysisAndAppearanceOfTransformationProducts</p>
<p>Total recovery of test substance (in %)</p>	<p>For each pH and temperature condition, indicate the total recovery in % of initial concentration (with standard deviation) or range if reported so. Copy this block of fields as necessary.</p>		<p>ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.TotalRecoveryOfTestSubstance</p>
<p>% Recovery</p>	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is</p>	<p>Range (Decimal)</p>	<p>ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.TotalRecoveryOfTestSubstance.Recovery</p>

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	'<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.TotalRecoveryOfTestSubstance.StDev
pH	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.TotalRecoveryOfTestSubstance.Ph
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.TotalRecoveryOfTestSubstance.Temp
Duration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.TotalRecoveryOfTestSubstance.Duration
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.TotalRecoveryOfTestSubstance.RemarksOnResults

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	<p>selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or</p> <p>- entering any additional information by selecting 'other:'</p> <p>NOTE: The phrase 'hydrolytically stable based on preliminary test' should be selected if applicable.</p>		
Total recovery of test substance (in %)			
Dissipation DT50 of parent compound	<p>Indicate the half-lives measured at different pH values and temperature as well as the extrapolated results for 25 degrees Celsius where applicable. Copy this block of fields for each test condition as appropriate.</p> <p>For robust study summaries or as requested by the regulatory programme, fill in also subfields 'Regression equation and r²' and 'DT90' (with unit) if available.</p>		<p>ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.DissipationHalfLifeOfParentCompound</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific</p>	<p>Check box</p>	<p>ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.DissipationHalfLifeOfParentCompound.KeyResult</p>

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	guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.		
pH	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.DissipationHalfLifeOfParentCompound.Ph
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.DissipationHalfLifeOfParentCompound.Temp
Hydrolysis rate constant	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.DissipationHalfLifeOfParentCompound.HydrolysisRateConstant
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.DissipationHalfLifeOfParentCompound.HalfLife
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.Dissipation

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			HalfLifeOfParentCompound.StDev
Type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.DissipationHalfLifeOfParentCompound.Type
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' NOTE: The phrase 'hydrolytically stable based on preliminary test' should be selected if applicable.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.DissipationHalfLifeOfParentCompound.RemarksOnResults
Dissipation DT50 of parent compound			
Other kinetic parameters	Describe any other kinetic parameters, if relevant.	Text area	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.OtherKineticParameters
Details on results	Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt	Text template	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.DetailsOnResults

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	<p>from the study report. TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered. MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table. Distinguish between dark and irradiated samples; compare the transformation products formed in the dark and irradiated samples, and identify and quantify the products that are formed by phototransformation only. As appropriate attach Figure showing the pathway of phototransformation of the test substance. SUPPLEMENTARY</p>		
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	EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.		
Results with reference substance	If reference substance(s) was/were tested, indicate whether the results with it/them are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.ResultsWithReferenceSubstance
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Hydrolysis.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Hydrolysis.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Hydrolysis.ApplicantSummaryAndConclusion

7.2.1.2 Direct and indirect photochemical degradation – Endpoint summary

<p>Purpose: Summary information of the most relevant study(ies) from which the key value for environmental fate and chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:</p> <ul style="list-style-type: none"> - amounts of test substance given as % of applied initial concentration and given as mg/l - transformation half-life or DT50 - related conditions (temperature, pH) - Identity of degradation products (if any)

ENDPOINT_SUMMARY.PhototransformationInWater v5.0 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Multiple endpoint summaries can be created where different DegT50 values are defined at different pH values. The pH should be specified in the 'Description of key	Header 1	ENDPOINT_SUMMARY.PhototransformationInWater.AdministrativeDataSummary

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		Confidentiality	ENDPOINT_SUMMARY.PhototransformationInWater.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)	Provide here the link to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.	Header 1	ENDPOINT_SUMMARY.PhototransformationInWater.LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	ENDPOINT_SUMMARY.PhototransformationInWater.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.PhototransformationInWater.LinkToRelevantStudyRecord.Results
Description of key information	<p>Enter a short description of the most relevant endpoint data. The short description could include for example:</p> <ul style="list-style-type: none"> -the test guideline used, -the test organism, -the exposure duration, -the contextual information of the origin of the value, -qualitative characterisation of some properties <p>Examples:</p> <ul style="list-style-type: none"> -“Melting point: 54.6-55.8 °C at 1,013 hPa (EEC Guideline A.1: Thermal analyses (Differential scanning calorimetry (DSC))” -“Short term toxicity to fish: LC50 (96h) < 100 mg/l for Pimephales promelas (OECD TG 203, static)” 	Header 1	ENDPOINT_SUMMARY.PhototransformationInWater.KeyInformation

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		Rich text area	ENDPOINT_SUMMARY.PhototransformationInWater.KeyInformation.KeyInformation
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.PhototransformationInWater.KeyValueForChemicalSafetyAssessment
Half-life in water		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.PhototransformationInWater.KeyValueForChemicalSafetyAssessment.HalfLifeInWater
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Header 1	ENDPOINT_SUMMARY.PhototransformationInWater.Discussion
	Provide any additional information related to the endpoint.	Rich text area	ENDPOINT_SUMMARY.PhototransformationInWater.Discussion.Discussion

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<p>Attached background material</p>	<p>Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.</p>		<p>ENDPOINT_SUMMARY.PhototransformationInWater.Discussion.AttachedBackgroundMaterial</p>
<p>Attached document</p>	<p>Provide any additional documents relevant for the submission, not already provided under the methods or results section or in the full study report. Choose the type of document from the picklist or select 'other:'.</p> <p>Examples are:</p> <ul style="list-style-type: none"> - Scientific publication - GLP documentation - (Q)SAR: supporting information - Data analysis file (calculation of parameters) - Data supporting the reliability and sensitivity of the method - Specific information on the test material or test system - Justification - Other <p>For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be</p>	<p>Single file attachment</p>	<p>ENDPOINT_SUMMARY.PhototransformationInWater.Discussion.AttachedBackgroundMaterial.AttachedDocument</p>

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	uploaded here if not yet done in the results section.		
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	ENDPOINT_SUMMARY.PhototransformationInWater.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	If required, an electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. These attachments should be sanitised if needed.	Attachments list	ENDPOINT_SUMMARY.PhototransformationInWater.Discussion.AttachedSanitisedDocsForPublication

7.2.1.2 Direct and indirect photochemical degradation – Endpoint summary

Purpose:

Summary information of the most relevant study(ies) from which the key value for environmental fate and chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:

- amounts of test substance given as % of applied initial concentration and given as mg/l
- transformation half-life or DT50
- related conditions (temperature, pH)
- Identity of degradation products (if any)

ENDPOINT_SUMMARY.PhototransformationInWater v5.0 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block Multiple endpoint summaries can be created where different DegT50 values are defined at different pH values. The pH should be specified in the 'Description of key	Header 1	ENDPOINT_SUMMARY.PhototransformationInWater.AdministrativeDataSummary

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Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.PhototransformationInWater.KeyValueForChemicalSafetyAssessment
Half-life in water		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.PhototransformationInWater.KeyValueForChemicalSafetyAssessment.HalfLifeInWater
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.PhototransformationInWater.Discussion

7.2.1.2 Direct and indirect photochemical degradation – Endpoint study record

Purpose:

The purpose of phototransformation studies in water is to determine the potential effects of solar irradiation on chemical pollutants in surface water. Studies determine phototransformation kinetics, products, and product pathways resulting either from direct or indirect (by photosensitizing or reaction with oxidizing transients) aqueous photolysis.

For compounds with a molar (decadic) absorption coefficient (ϵ) $> 10 \text{ L} \times \text{mol}^{-1} \times \text{cm}^{-1}$ at a wavelength (λ) $\geq 295 \text{ nm}$ direct phototransformation of purified active substances shall be determined and reported unless the applicant shows that contamination of surface water will not occur.

Studies on direct photochemical degradation shall also be performed for metabolites, breakdown and reaction products which account at any time for more than 10 % of the amount of active substance added in the photolysis study, unless sufficient information on their degradation is available from the test performed with the active substance.

No additional photolysis information on degradates shall be required if they are considered to be stable under photolytic conditions.

The direct phototransformation in purified, (for example distilled) buffered water using artificial light under sterile conditions, if necessary using a solubiliser, shall be determined and reported. In the first theoretical step a maximum possible photolysis rate shall be estimated based on the molar extinction coefficient of the active substance. If photolysis is considered to be a potentially significant degradation pathway, photolysis experiments for range finding shall be carried out (tier 2). Determination of quantum yield and direct photolysis route/rate (tiers 3 and 4) shall be carried out for active substances where tier 2 indicates significant photolysis. The identity of breakdown products formed which exceed 10 % of the applied test substance at any time during the study, a mass balance to account for at least 90 % of the applied radioactivity, as well as photochemical half-life (DT50) shall be reported.

ENDPOINT_STUDY_RECORD.Phototransformation v7.3 (Final)

Name	Instructions	Data type	Field path
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Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Phototransformation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Phototransformation.DataSource
Materials and methods	Material and methods – common block Applicable Test guideline: OECD Test Guideline 316: Phototransformation of Chemicals in Water - Direct Photolysis	Header 1	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.Radiolabelling
Analytical method	Indicate which method was used. Multiple selection is possible. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on sampling	Enter details on sampling regime and method. Use freetext template as appropriate.	Text template	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.DetailsOnSampling
Details on analytical methods	If the amount of test material in the test	Text template	ENDPOINT_STUDY_RECORD.Phototransformation.M

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	<p>solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products.</p>		<p>aterialsAndMethods.Study Design.DetailsOnAnalytical Methods</p>
Buffers	<p>Using freetext template give details on the buffer(s) used for each nominal pH tested; copy any subheading(s) as appropriate for indicating buffers at different pH values.</p>	Text template	<p>ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.Study Design.Buffers</p>
Light source	<p>Select light source used.</p>	Open list with remarks	<p>ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.Study Design.LightSource</p>
Light spectrum: wavelength in nm	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range (Decimal)	<p>ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.Study Design.LightSpectrumWavelengthInNm</p>

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Relative light intensity	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.RelativeLightIntensity
Details on light source	Enter any relevant details on the light source. Use either of the two freetext templates as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.DetailsOnLightSource
Sensitiser (for indirect photolysis)			ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.SensitiserForIndirectPhotolysis
Type of sensitiser	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.SensitiserForIndirectPhotolysis.TypeOfSensitiser
Details on sensitiser	Provide details on sensitiser as appropriate.	Text	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.SensitiserForIndirectPhotolysis.DetailsOnSensitiser
Concentration of sensitiser	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>='	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.SensitiserForIndire

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	or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		ctPhotolysis.ConcentrationOfSensitiser
Sensitiser (for indirect photolysis)			
Details on test conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions
Duration of test at given test condition			ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Duration
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Temp
Initial conc. measured	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.InitialConcMeasured
Duration of test at given test condition			

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Reference substance	Indicate if test(s) with a substance with known photolysis was performed. If yes, report the identity of the substance in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.ReferenceSubstance
Dark controls	Indicate if dark, i.e. negative controls were used in parallel studies. Remarks can be included in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.DarkControls
Computational methods	Enter details on computational methods used to calculate relevant parameters. Use freetext template as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.StudyDesign.ComputationalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Phototransformation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion
Preliminary study	Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.PreliminaryStudy
Test performance	Report on any unusual observations during test, deviations from test procedure or any	Multi-line text	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.TestPerformance

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	other information affecting results.		
Spectrum of substance			ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.SpectrumOfSubstance
Parameter	Select parameter from drop-down list and enter the corresponding value or range with unit (unless dimensionless) in the related text field, together with any explanation if necessary, e.g. on the study group the result refers to. Explanations: AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration.	Open list	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.SpectrumOfSubstance.Parameter
Value	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.SpectrumOfSubstance.Value
Remarks	Enter any remarks related to the recorded value as appropriate.	Text	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.SpectrumOfSubstance.Remarks

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Spectrum of substance			
% Degradation	Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.Degradation
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.Degradation.KeyResult
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.Degradation.Degr
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.Degradation.StDev
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.Degradation.SamplingTime

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Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.Degradation.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Quantum yield (for direct photolysis)	For direct photolysis only, give the reaction quantum yield of the test substance (values between 0 and 1).	Decimal	ENDPOINT_STUDY_RECORD.Phototransformation.QuantumYield
Rate constant (for indirect photolysis)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.RateConstant

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	the appropriate qualifier(s) if applicable.		
Dissipation half-life of parent compound			ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.DissipationParentCompound
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.DissipationParentCompound.KeyResult
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.DissipationParentCompound.DT50
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.DissipationParentCompound.TestCondition
Remarks on result	This field can be used for:	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Phototransformation.R

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	<ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' 		<p>resultsAndDiscussion.DissipationParentCompound.RemarksOnResults</p>
Dissipation half-life of parent compound			
Predicted environmental photolytic half-life	<p>Include the predicted environmental photolytic half-life derived from the measured half-life in a sterile buffer solution, if provided. State for which latitude, time of day, season, location etc. the estimation was made.</p>	Multi-line text	<p>ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.PredictedEnvironmental</p>
Transformation products	<p>Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.</p>	Closed list with remarks	<p>ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.TransformationProducts</p>

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Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transformation products			

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<p>Details on results</p>	<p>Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Explanations on freetext prompts:</p> <p>TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.</p> <p>HALF-LIFE: Include a table with detailed results for dark and irradiated samples including Regression equation, r^2 and DT90 if available.</p> <p>MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECO RD.Phototransformation.R resultsAndDiscussion.Detail sOnResults</p>
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	<p>'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table. Distinguish between dark and irradiated samples; compare the transformation products formed in the dark and irradiated samples, and identify and quantify the products that are formed by phototransformation only. As appropriate attach Figure showing the pathway of phototransformation of the test substance. SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.</p>		
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.ResultReferenceSubstance
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Phototransformation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Phototransformation.O verallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Phototransformation.A pplicantSummaryAndConcl usion

7.2.2 Route and rate of biological degradation in aquatic systems

7.2.2.1 Ready biodegradability and degradation in the saturated zone - Endpoint summary

<p>Purpose: Summary information of the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Enter a short description of the most relevant endpoint data. The short description could include for example:</p> <ul style="list-style-type: none"> - the test guideline used, - related conditions (e.g. temperature, a.s. concentration) - test samples used - rate of degradation - pathway(s) - measurement uncertainty if available;

ENDPOINT_SUMMARY.BiodegradationInWaterScreeningTests v.7.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY. BiodegradationInWater ScreeningTests.Adminis trativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY. BiodegradationInWater ScreeningTests.KeyValu eForChemicalSafetyAss essment
Biodegradation in water		Closed list	ENDPOINT_SUMMARY. BiodegradationInWater ScreeningTests.KeyValu eForChemicalSafetyAss essment.Biodegradation InWater
Type of water	Choose the type of water of the most relevant study.	Open list	ENDPOINT_SUMMARY. BiodegradationInWater ScreeningTests.KeyValu

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			eForChemicalSafetyAssessment.TypeOfWater
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY. BiodegradationInWater ScreeningTests.Discussion

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7.2.2.1 Ready biodegradability and degradation in the saturated zone – Endpoint study record

Purpose:

The persistence and behaviour of plant protection products in open water (freshwater, estuarine and marine) shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.2.2.2 of Part A of the Annex to Regulation (EU) No 283/2013.

The test shall be reported unless the applicant shows that contamination of open water will not occur. The rate of degradation and the pathway or pathways shall be reported either for a 'pelagic' test system or for a 'suspended sediment' system. Where relevant, additional test systems, which differ with respect to organic carbon content, texture or pH shall be used.

Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and, where relevant, sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂ ;
- (c) volatile compounds other than CO₂ ;
- (d) individual identified transformation products;
- (e) extractable substances not identified; and
- (f) non-extractable residues in sediment.

The duration of the study shall not exceed 60 days unless the semi-continuous procedure with periodical renewal of the test suspension is applied. However, the period for the batch test may be extended to a maximum of 90 days, if the degradation of the test substance has started within the first 60 days.

ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests v.6.3 (Final) [September 2020]

Name	Instructions	Data type	Field path	Containing Block name
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.AdministrativeData	Administrative data record block
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.Data Source	Data source block (Literature Reference)
Materials and methods	Material and methods – common block Applicable Test guideline: OECD Test Guideline 309: Aerobic	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods	

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	<p>Mineralisation in Surface Water - Simulation Biodegradation Test</p> <p>ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment</p>			
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.TestMaterials	Test materials block
Study design		Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign	
Oxygen conditions	<p>Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.OxygenConditions	
Inoculum or test system	<p>Select the inoculum used. As far as possible, indicate whether any activated sludge or sewage used was adapted or not. If the study report does not give clear</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.InoculumOrTestSystem	

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	<p>information thereof, select '..... (adaptation not specified)', e.g. 'sewage, domestic (adaptation not specified)'. In this case, give further explanation in field 'Details on inoculum', if any. In field 'Rationale for reliability', discuss the impact of this reporting deficiency on the study results. If no inoculum was added in the strictest sense, but natural water and/or sediment was used, indicate the corresponding test system, e.g. 'natural water / sediment'. Note that any simulation tests should be recorded using the corresponding template.</p>			
Details on inoculum	Give details on inoculum as appropriate. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.DetailsOnInoculum	
Duration of test (contact time)	Enter a single numeric value in the first numeric field if you select no qualifier or '>',	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.S	

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	'>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		tudyDesign.Durati onOfTestContactTi me	
Initial test substance concentration	Specify the initial test concentration applied. If different concentrations were used in different test runs, copy this block of fields accordingly. If a range of concentrations is reported, include the lower and upper values in the numeric range field. If appropriate copy this block of fields for indicating different parameters the initial concentration is based on (e.g. COD and test substance).		ENDPOINT_STUD Y_RECORD.Biodeg radationInWaterSc reeingTests.Mate rialsAndMethods.S tudyDesign.Initial TestSubstanceCon centration	
Initial conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<'	Range with open list (Decimal)	ENDPOINT_STUD Y_RECORD.Biodeg radationInWaterSc reeingTests.Mate rialsAndMethods.S tudyDesign.Initial TestSubstanceCon centration.InitialC onc	

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	or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.			
Based on	From drop-down list, select the parameter on which the initial concentration is based.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.BasedOn	
Initial test substance concentration				
Parameter followed for biodegradation estimation	Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as appropriate. In supplementary remarks field, give relevant details on the method. For radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.ParameterFollowedForBiodegradationEstimation	
Parameter followed for biodegradation estimation	Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.ParameterFollowedForBi	

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	appropriate. In supplementary remarks field, give relevant details on the method. For radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.		odegradationEstimation.ParameterFollowedForBiodegradationEstimation	
Parameter followed for biodegradation estimation				
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods	
Details on study design	Use freetext template and delete/add elements as appropriate. Enter	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.S	

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	any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		tudyDesign.Details OnStudyDesign	
Reference substance	Indicate identity of reference substance(s) used and give details in the supplementary remarks field as appropriate. Repeat field for each substance.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.StudyDesign.ReferenceSubstance	
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables	Any other information on materials and methods incl. tables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion	
Preliminary study	Describe relevant results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.PrelimStudyRs	
Test performance	Report on any unusual observations during test or any other information affecting results. Give reasons for any rejection of	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.TestPerformance	

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	<p>the test results if applicable. Note that any deviations from test procedure should be briefly stated in field 'Deviations from guideline'.</p>			
% Degradation	<p>Indicate percentage of degradation of test substance including standard deviation at the end of the study period. Indicate the parameter the percentage is based on and the sampling time. Copy this block of fields for recording the percentage values for different parameters. Note that the degradation at different sampling time points (raw data) should be recorded in below field 'Details on results'. Note: BOD*100/COD results should be entered in the respective fields below. Note: In the case of QSAR/QSPR results, the parameter 'probability of</p>		<p>ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation</p>	

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	ready biodegradability (QSAR)', 'calculated rating of total degradation time (QSAR/QSPR)' or 'half-life in days (QSAR/QSPR)' can be selected if applicable, and the relevant value entered in field 'Value'.			
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.KeyResult	
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.Parameter	
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.Degr	

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	the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.			
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.StDev	
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.SamplingTime	
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Degradation.RemarksOnResults	
% Degradation				

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<p>Details on results</p>	<p>Record the degradation / elimination kinetics for the different types of test suspensions, i.e. percentage of degradation at different sampling time points. For robust study summaries or as requested by the regulatory programme, include table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). In field 'Attached background material', attach graph(s) with the full degradation or elimination curves for the test and reference substances, the lag phase, degradation phase, the 10-d window and slope. For tests for ready biodegradability,</p>	<p>Text area</p>	<p>ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.ResultsDetails</p>	
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	<p>in which oxygen consumption is used as analytical method (e.g. MITI method), a BOD curve against time should be attached. If requested by the regulatory programme, also include a table on the material (mass) balance of parent compound and transformation products and a table showing the percentage data for degradability measured as BOD, DOC and by specific chemical analysis (see predefined tables).</p>			
BOD5 / COD results	<p>For BOD5 tests, copy this block of fields for entering BOD5 and COD values (or ranges if reported so) including the unit, and the ratio $BOD5 \times 100 / COD$ (with no unit). If a BOD5/COD or BOD5/ThOD ratio is reported, multiply the original value by 100. Include any raw data in field 'Any other information</p>	Header 2	<pre>ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults</pre>	

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	on results incl. tables'.			
BOD5 / COD	For BOD5 tests, copy this block of fields for entering BOD5 and COD values (or ranges if reported so) including the unit, and the ratio BOD5*100/COD (with no unit). If a BOD5/COD ratio is reported, multiply the original value by 100. Include any raw data in field 'Any other information on results incl. tables'.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod.KeyResult	
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod.Parameter	

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Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod.Value	
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Bod5Cod.RemarksOnResults	
BOD5 / COD				
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.Bod5CodResults.Re	

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			sultsWithReferenceSubstance	
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables	Any other information on results incl. tables Block
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.OverallRemarksAttachments	Overall remarks, attachments block
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterScreeningTests.ApplicantSummaryAndConclusion	Applicant's summary and conclusion block

7.2.2.2 Biodegradation in water, sediment and surface water

Biodegradation in water and sediment: simulation tests (EU PPP) – Endpoint summary

Purpose:

Chemical: To conclude on the persistence of the active substance or product in aquatic systems. Derivation of DT50, DT90, Kinetic parameters and formation fraction in water, sediment or the whole system from the submitted endpoint studies.

The following endpoints are covered by this summary document: Water/sediment study, Irradiated water/sediment study.

ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP v1.3 (Final)

Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.AdministrativeDataSummary

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Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa
Persistence / rate of degradation in freshwater	Report persistence endpoints for parent compound and metabolites in the water column.		ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.Substance
pH	Enter the pH value of the water phase in the laboratory test system.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.PH
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the pH was measured.	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.MeasuredIn
Half-life in freshwater	Enter the DT50 value for persistence in the water column.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyV

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			alueCsa.PersistenceDegradationFreshwater.HalfLifeFreshWater
DT90 in freshwater	Enter the DT90 value for persistence in the water column.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.DtNinetyFreshwater
at the temperature of	Enter the temperature of the test system in the laboratory.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.Temperature
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for persistence.	Decimal	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDegradationFreshwater.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.PersistenceDe

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			gradationFreshwater.K ineticFormationFractio n
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.PersistenceDe gradationFreshwater.P recursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.PersistenceDe gradationFreshwater.R emarks
Persistence / rate of degradation in freshwater			
Modelled rate of degradation in freshwater	Report modelling endpoints for parent compound and metabolites in the water column. Note that modelling endpoints are not routinely completed for the water column.		ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.ModelledDegr adationFreshwater
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.ModelledDegr adationFreshwater.Par entMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.ModelledDegr adationFreshwater.Sub stance

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pH	Enter the pH value of the water phase in the laboratory test system.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the water pH was measured.	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.MeasuredIn
Normalised (DT50)	Enter the DT50 value in water column for modelling at 20°C, normalized using a Q10 of 2.58.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.NormalisedDtFifty
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for modelling.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.ChiSquare
Method of calculation	For normalised DT50 (modelling endpoint), when biphasic kinetic is used, it should be specified how the DT50 was derived (DT90FOMC/3.32, DFOP slow phase, etc.)	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.KineticParameters

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Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.Precursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.ModelledDegradationFreshwater.Remarks
Modelled rate of degradation in freshwater	Rate of degradation in marine water is not relevant for PPP authorization.		
Rate of degradation in marine water	Rate of degradation in marine water is not relevant for PPP authorization.	Header 2	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater
Half-life in marine water		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.HalfLifeMarineWater
at the temperature of	Enter the temperature of the test system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationM

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			arineWater.Temperature
Persistence / rate of degradation in freshwater sediment	Report persistence endpoints for parent compound and metabolites in the sediment.		ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.Substance
pH	Enter the pH value of the sediment in the laboratory test system.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the sediment pH was measured.	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.MeasuredIn

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Half-life in freshwater sediment	Enter the DT50 value for persistence in sediment.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.HalfLifeFreshwaterSediment
DT90 in freshwater sediment	Enter the DT90 value for persistence in sediment.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.DTNinetyFreshwaterSediment
at the temperature of	Enter the temperature of the test system in the laboratory.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.Temperature
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwaterSediment.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP,HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.PersistenceDegradationFreshwater

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			rSediment.Calculation Method
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.Persistence DegradationFreshwaterSediment.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.Persistence DegradationFreshwaterSediment.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.Persistence DegradationFreshwaterSediment.Precursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.Persistence DegradationFreshwaterSediment.Remarks
Persistence / rate of degradation in freshwater sediment	Report half-life and related measurements for sediment		
Modelled rate of degradation in freshwater sediment	Report modelling endpoints for parent compound and metabolites in the sediment.		ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyV

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	Note that modelling endpoints are not routinely completed for the sediment.		alueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.Substance
pH	Enter the pH value of the sediment in the laboratory test system	Decimal	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the sediment pH was measured.	Multi-line text	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.MeasuredIn
Normalised (DT50)	Enter the DT50 value for modelling at 20°C, normalized using a Q10 of 2.58.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledD

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			egradationFreshwater Sed.NormalisedDtFifty
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.ChiSquare
Method of calculation	For normalised DT50 (modelling endpoint), when biphasic kinetic is used, it should be specified how the DT50 was derived (DT90FOMC/3.32, DFOP slow phase, etc.)	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.Precursor

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Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineWater.ModelledDegradationFreshwaterSed.Remarks
Modelled rate of degradation in freshwater sediment			
Rate of degradation in marine water sediment	Rate of degradation in marine water sediment is not relevant for PPP authorization.	Header 2	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment
Half-life in marine water sediment		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.HalfLifeMarineWaterSed
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.Temperature
Persistence / rate of degradation in whole system	Report persistence endpoints for parent compound and metabolites in the whole system.		ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyV

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			alueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.Substance
pH		Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water).	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.MeasuredIn
Half-life in freshwater	Enter the DT50 value for persistence in the whole system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.PersistenceDegradationWholeSystem.HalfLifeFreshWater
DT90 in freshwater	Enter the DT90 value for persistence in the whole system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationM

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			arineSediment.Persist nceDegradationWhole System.DtNinetyFresh water
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.DegradationM arineSediment.Persist nceDegradationWhole System.Teperature
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for persistence.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.DegradationM arineSediment.Persist nceDegradationWhole System.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP,HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.DegradationM arineSediment.Persist nceDegradationWhole System.CalculationMet hod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.DegradationM arineSediment.Persist nceDegradationWhole System.KineticParamet ers
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.DegradationM

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			arineSediment.Persist nceDegradationWhole System.KineticFormati onFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.DegradationM arineSediment.Persist nceDegradationWhole System.Precursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.DegradationM arineSediment.Persist nceDegradationWhole System.Remarks
Persistence / rate of degradation in whole system	Report half-life and related measurements for the whole system		
Modelled rate of degradation in whole system	Report modelling endpoints for parent compound and metabolites in the whole system.		ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.DegradationM arineSediment.Modelle dDegradationWholeSy stem
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV alueCsa.DegradationM arineSediment.Modelle dDegradationWholeSy stem.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWate rAndSedimentSimulati onTests_EU_PPP.KeyV

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			alueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.Substance
pH		Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water).	Multi-line text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.MeasuredIn
Normalised (DT50)	Enter the DT50 value in whole system for modelling at 20°C, normalized using a Q10 of 2.58.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.NormalisedDtFifty
Chi-square (χ^2)	Chi-square value of the DT50. Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for modelling.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.ChiSquare
Method of calculation	For normalised DT50 (modelling endpoint), when biphasic kinetic is used, it should be specified how the DT50 was derived (DT90FOMC/3.32, DFOP slow phase, etc.)	Text	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.Modelled

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			dDegradationWholeSystem.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha,beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products, arithmetic mean.	Decimal	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.KineticFormationFraction
Precursor	For metabolites, when relevant, select the substance for the precursor.	Entity reference field	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.Precursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulationTests_EU_PPP.KeyValueCsa.DegradationMarineSediment.ModelledDegradationWholeSystem.Remarks
Modelled rate of degradation in whole system			
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY .BiodegradationInWaterAndSedimentSimulati

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			onTests_EU_PPP.Discussion
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Links to support material:

FOCUS, 2006. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference SANCO/10058/2005-v. 2.0, 434 pp., as updated by the Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, v. 1.1, December 2014.

Route of biodegradation in water, sediment and surface water – Endpoint summary

Purpose:

Chemical: Conclude on the route of degradation of the active substance or product. Derivation of the proportion and the maximum occurrence of components considering the submitted endpoint studies

ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP v1.2 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a
Route of degradation in freshwater			ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.Substance
pH	Measured in e.g. calcium chloride solution, water.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreshwater.Ph

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Mineralisation (%)	Percent mineralisation after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationFreshwater.Mineralisation
Non extractable residues (%)	Percent non-extractable residues after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationFreshwater.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationFreshwater.MaximumOccurrence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationFreshwater.DayMaximumOccurrence
Actual duration (days)	Report the duration of the study in days.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationFreshwater.ActualDuration
Radio label	Provide information on the radio labelling used to obtain these results	Text	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationFreshwater.RadioLabel
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationFreshwater.Remarks
Route of degradation in freshwater			
Route of degradation in marine water			ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationMarineWater
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationMarineWater.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs.a.RouteDegradationMarineWater.Substance

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pH	Measured in e.g. calcium chloride solution, water.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.Ph
Mineralisation (%)	Percent mineralisation after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.Mineralisation
Non extractable residues (%)	Percent non-extractable residues after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.MaximumOccurrence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.DayMaximumOccurrence
Actual duration (days)		Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.ActualDuration
Radio label		Text	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.RadioLabel
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWater.Remarks
Route of degradation in marine water			
Route of degradation in freshwater sediment			ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.ParentMetabolite

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Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.Substance
pH	Measured in e.g. calcium chloride solution, water.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.Ph
Mineralisation (%)	Percent mineralisation after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.Mineralisation
Non extractable residues (%)	Percent non-extractable residues after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.MaximumOccurrence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.DayMaximumOccurrence
Actual duration (days)		Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.ActualDuration
Radio label		Text	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.RadioLabel
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationFreswaterSediment.Remarks
Route of degradation in freshwater sediment			
Route of degradation in marine water sediment			ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment

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Parent / metabolite		Closed list	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.Substance
pH	Measured in e.g. calcium chloride solution, water.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.Ph
Mineralisation (%)	Percent mineralisation after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.Mineralisation
Non extractable residues (%)	Percent non-extractable residues after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.MaximumOccurrence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.DayMaximumOccurrence
Actual duration (days)		Integer	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.ActualDuration
Radio label		Text	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.RadioLabel
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP.KeyValueCs a.RouteDegradationMarineWaterSediment.Remarks
Route of degradation in			

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marine water sediment			
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.RouteDe gWaterSed_EU_PPP.Discussion
Attached (sanitised) documents for publication	<p>A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.</p> <p>For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section.</p>	Attachments list	ENDPOINT_SUMMARY.RouteDe gWaterSed_EU_PPP.Discussion. AttachedSanitisedDocsForPublica tion

Links to support material:

ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment (revision 3, June 2017)
 DG SANCO Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides" (25.09.2012 – rev. 3)

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Route and rate of biodegradation in water, sediment and surface water - Endpoint study record

Purpose:

Information should be reported on:

Chemicals: identify and characterise the components present, establish the relative proportions of the components (mass balance). The degradation pathway or pathways shall be reported for two water/sediment systems. The two sediments selected shall differ with respect to organic carbon content and texture, and where relevant, with respect to pH. Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and sediment as a function of time.

Microorganisms: viability/population dynamics in natural sediment/water systems under both dark and illuminated conditions.

ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests v.7.4			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test OECD Test Guideline 308: Aerobic and	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods

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	Anaerobic Transformation in Aquatic Sediment Systems Method C.4 Determination of "ready" biodegradability (Annex to Regulation (EC) No 440/2008) OECD Guideline Test 301: Ready Biodegradability (301 A - F) OECD Test Guideline 310: Ready Biodegradability - CO ₂ in sealed vessels (Headspace Test) Microbial Pesticide Test Guidelines OPPTS 885.5300 Expression in a Freshwater Environment		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.TestMaterials.Radiolabelling

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Study design		Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign
Oxygen conditions	Indicate whether test was performed under aerobic or anaerobic conditions. Select 'aerobic/anaerobic' if both oxygen conditions occur as in water/sediment studies. If 'aerobic (low dissolved oxygen)' applies, specify in the supplementary remarks field or in the field 'Details on study design' that the O ₂ concentration was controlled. Include any explanations in the supplementary remarks field as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.OxygenConditions
Inoculum or test system	Select the inoculum used. As far as possible, indicate whether any activated sludge or sewage used was adapted or not. If the study report does not give clear information thereof, select '..... (adaptation not specified)', e.g. 'sewage, domestic (adaptation not specified)'. In this case, give further explanation in field 'Details on inoculum', if any. In field 'Rationale for reliability', discuss the impact of this reporting	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.InoculumOrTestSystem

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	<p>deficiency on the study results.</p> <p>If no inoculum was added in the strictest sense, but natural water and/or sediment was used, indicate the corresponding test system, e.g. 'natural water / sediment'.</p> <p>Note that any simulation tests should be recorded using the corresponding template.</p>		
Details on source and properties of surface water	<p>Give details on source and properties of surface water used as inoculum if applicable. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnSourceAndPropertiesOfSurfaceWater
Details on source and properties of sediment	<p>Give details on source and properties of sediment used as inoculum if applicable. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnSourceAndPropertiesOfSediment
Details on inoculum	<p>Give details on any other inoculum, e.g. wastewater, activated sludge, anaerobic sludge if applicable. Use either freetext template 1 (activated sludge) or 2 (other) and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnInoculum
Duration of test (contact time)	<p>Enter a single numeric value in the first numeric field if you select no qualifier or</p>	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsA

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	'>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		ndMethods.StudyDesign.DurationOfTestContactTime
Initial test substance concentration	Specify the initial test concentration applied. If different concentrations were used in different test runs, copy this block of fields accordingly. If a range of concentrations is reported, include the lower and upper values in the numeric range field. If appropriate copy this block of fields for indicating different parameters the initial concentration is based on (e.g. COD and test substance).		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration
Initial conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.InitialConc
Based on	From drop-down list, select the parameter on which the initial concentration is based.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.BasedOn

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Initial test substance concentration			
Parameter followed for biodegradation estimation	<p>Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as appropriate. In the supplementary remarks field, give relevant details on the method. Indicate if total mineralisation was determined if applicable. Specify if the radioactivity was recovered as parent and/or metabolite or associated with biomass. For further relevant details on radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.ParameterFollowedForBiodegradationEstimation
Details on analytical methods	<p>If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products and/or non-extractable residues.</p>	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods

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	Specify methods for water and sediment if applicable.		
Details on study design	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnStudyDesign
Reference substance	Indicate identity of reference substance(s) used and give details in the supplementary remarks field as appropriate. Repeat field for each substance.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.ReferenceSubstance
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion
Test performance	Report on any unusual observations during test or any other information affecting results. Give reasons for any rejection of the test results if applicable. Note that any deviations from test procedure should be briefly stated in field	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.TestPerformance

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	'Deviations from guideline'.		
Mean total recovery	If applicable, indicate mean total recovery of test material as percentage of applied amount in water and/or sediment +/- standard deviation. If relevant, also specify 'Total recovery in abiotic control measured at end of test' and 'Total recovery in biologically active treatment at end of test'.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery
Compartment	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.Compartment
Sampling date		Date	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.SamplingDate
% Total extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.TotalExtractable
% Non extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.NonExtractable

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	field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
% CO2	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.CO2
% Other volatiles	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.OtherVolatiles
% Recovery	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.Recovery
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.MeanTotalRecovery.StDev
Remarks on result	This field can be used for: - giving a qualitative description of results in	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAnd

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	<p>addition to or if no numeric value(s) were derived;</p> <ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' 		Discussion.MeanTotalRecovery.RemarksOnResults
Mean total recovery			
% Degradation	<p>Indicate percentage of degradation of test substance including standard deviation at the end of the study period. Indicate the parameter the percentage is based on and the sampling time. Copy this block of fields for recording the percentage values for different parameters. Note that the degradation at different sampling time points (raw data) should be recorded in below field 'Details on results'.</p>		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation
Parent/product	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.ParentProduct
Name or code for product	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.

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	available in the inventory, create a new one.		NameOrCodeForProduct
Compartment	Select from drop-down list.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.Compartment
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.KeyResult
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.Degr
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.StDev
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.Parameter
Sampling date	Enter a date (yyyy-mm-dd).	Date	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAnd

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			Discussion.Degradation.SamplingDate
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.SamplingTime
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Half-life of parent compound / 50% disappearance time (DT50)	Include value (or range if reported so) of half-life and indicate the type of half-life (For first order kinetics DT50 = half-life). For water-sediment systems repeat this block of fields for each compartment.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.KeyResult

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Compartment	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.Compartment
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.HalfLife
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.StDev
Type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.Type
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.Temp
Remarks on result	This field can be used for: - giving a qualitative	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSim

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	<p>description of results in addition to or if no numeric value(s) were derived;</p> <ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' 		<p>ulationTests.ResultsAnd Discussion.HalfLifeOfParentCompound50DisappearanceTimeDT50.RemarksOnResults</p>
Half-life of parent compound / 50% disappearance time (DT50)			
Mineralization rate (in CO₂)	Enter Mineralization rate (in CO ₂)	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAnd Discussion.MineralizationRateInCO ₂
Other kinetic parameters	Include any other relevant kinetic parameters if applicable. Select the respective item(s) from the multi-select picklist and include the value in the associated remarks field.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAnd Discussion.OtherKineticParameters
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAnd Discussion.TransformationProducts

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	Not relevant for microorganisms		
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.IdentityTran sformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.IdentityTran sformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.IdentityTran sformation.ReferenceSu bstance
Identity of transformation products			

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Details on transformation products	Indicate any relevant supplementary information on transformation products. Use freetext template and delete/add items as appropriate. If useful attach a figure in the corresponding field.	Text template	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.TransfProdu ctsDetails
Evaporation of parent compound	Indicate whether evaporation of the parent compound occurred or not. Include any explanations in field 'Details on results' as appropriate. 'Yes' should be selected when CO ₂ has been detected in volatile traps	Closed list with remarks	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.Evaporation OfParentCompound
Volatile metabolites	Indicate whether volatile metabolites were found or not. Include any explanations in field 'Details on results' as appropriate.	Closed list with remarks	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.VolatileMeta bolites
Residues	Indicate whether residues were found or not. Include any explanations in field 'Details on results' as appropriate.	Closed list with remarks	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.Residues
Details on results	Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich	Text template	ENDPOINT_STUDY_RE CORD.BiodegradationIn WaterAndSedimentSim ulationTests.ResultsAnd Discussion.DetailsOnRe sults

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	<p>text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>In field 'Attached background material', attach graph(s) with the full degradation or elimination curves.</p> <p>TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.</p> <p>MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected.</p> <p>Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table.</p> <p>STERILE TREATMENTS: If used, report the transformation of the</p>		
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	parent, and compare the results with those of the non-sterile treatments: SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.		
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.ResultsWithReferenceSubstance
Any other information on results incl. tables	Any other information on results incl. tables Block For Microorganisms the tables in the results and discussion section do not need to be reported unless suitable data is available. However Tabulation/graphs of population dynamics and Discussion of test results should be provided in this field.	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.AnyOtherInformationOnResultsInTables
Overall remarks, attachments	Overall remarks, attachments – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.OverallRemarksAttachments
Kinetic evaluation	The filled "Template 7.1 - template for	Attachment (multiple)	ENDPOINT_STUDY_RECORD.BiodegradationIn

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	presentation of kinetic fitting" (https://doi.org/10.5281/zenodo.4557253) shall be uploaded here to report the the visual and statistical kinetic evaluation.		WaterAndSedimentSimulationTests.OverallRemarksAttachments.KineticEvaluation
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ApplicantSummaryAndConclusion
Validity criteria	Include any validity criteria from the followed study guidance.		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ApplicantSummaryAndConclusion.ValidityCriteria
Validity criteria	Type in the addressed validity criteria.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ApplicantSummaryAndConclusion.ValidityCriteria.ValidityCriteria
Observed value	Type in the observation related to the respective validity criteria.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ApplicantSummaryAndConclusion.ValidityCriteria.ObservedValue

7.3.1 Route and rate of degradation in air – Endpoint summary

<p>Purpose Provide summary information of the most relevant study(-ies) from which the key value for assessment is extrapolated. Provide only the most relevant details related to the concentrations in air.</p>
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ENDPOINT_SUMMARY.PhototransformationInAir v.5.0			
Name	Instructions	Data type	Field path

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Administrative data	Administrative data summary – common block Conclude on direct photolysis in air, photochemical oxidative degradation in air and volatilization For microorganisms indicate if concentration in air are observed	Header 1	ENDPOINT_SUMMARY.Photo transformationInAir.AdministrativeDataSummary
Key value for chemical safety assessment	Only to be completed if such data exists	Header 1	ENDPOINT_SUMMARY.Photo transformationInAir.KeyValueForChemicalSafetyAssessment
Half-life in air		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Photo transformationInAir.KeyValueForChemicalSafetyAssessment.HalfLifeInAir
Degradation rate constant with OH radicals		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Photo transformationInAir.KeyValueForChemicalSafetyAssessment.DegradationRateConstantWithOHRadicals
Additional information	Discussion (Header 1) – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_SUMMARY.Photo transformationInAir.Discussion

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Links to support material:

Pesticides in Air: Considerations for Exposure Assessment”. Report of the FOCUS Working Group on Pesticides in Air (SANCO/10553/2006 Rev 2 June 2008)

https://esdac.jrc.ec.europa.eu/public_path/projects_data/focus/air/docs/FOCUS_AIR_GROUP_REPORT-FINAL.pdf

7.3.1 Route and rate of degradation in air - Endpoint study record

Purpose

Chemicals: An estimate of the half-life in the upper atmosphere of the active substance and any volatile metabolites, breakdown and reaction products, formed in soil or natural water systems, shall be calculated and reported.

Estimates of active substance upper atmospheric half-lives, based on monitoring data shall also be calculated, when monitoring data that enable this to be done, are available.

Microorganisms: In case of particular concerns for operator, worker or bystander exposure, information on the concentrations in air might be necessary.

ENDPOINT_STUDY_RECORD.PhototransformationInAir v.7.3			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.AdministrativeData
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.PhototransformationInAir.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAn

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			dMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Study design		Header 2	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign
Estimation method (if used)	If the photodegradation was estimated, e.g. the photochemical reaction with OH radicals, include details on the computational method used. Use freetext template as appropriate. As an alternative option, attach a document e.g. excerpt from the study report. Record the estimated half-life under 'Dissipation half-life of parent compound' in the Results section. Guidance on freetext template: - Concentration of OH radicals: e.g. '50000 molecules/cm ³ ' - Degradation rate constant: e.g. '18.3 x 10E-12 cm ³ /(molecule*sec)' - Temperature for which rate constant was calculated: e.g. '25 °C' - Computer programme: e.g. 'EPIWIN, part AOPWIN v.1.90. (2000)' or 'AOP based on SAR methods developed by Atkinson'	Text template	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.EstimationMethodIfUsed
Light source	Select light source used.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.LightSource
Light spectrum : wavelength in nm	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.LightSpectrumWavelengthInNm
Relative light intensity	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.RelativeLightIntensity

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Details on light source	Enter any relevant details on the light source. Use either of the two freetext templates as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DetailsOnLightSource
Details on test conditions	Briefly describe the experimental set-up and procedure used.	Text area	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions
Duration of test at given test condition	Indicate the test duration, temperature and initial test substance concentration at which test was conducted. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Duration
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Temp
Initial conc. measured	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.InitialConcMeasured
Duration of test at given test condition			

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Reference substance	Indicate whether the results with the reference substance(s) are valid.	Close list with remarks	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.StudyDesign.ReferenceSubstance
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.PhototransformationInAir.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion
Preliminary study	Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.PreliminaryStudy
Test performance	Report on any unusual observations during test, deviations from test procedure or any other information affecting results.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.TestPerformance
Spectrum of substance	Select spectral parameter from picklist and enter value in the subsequent subfield. Any notes can be included in subfield 'Remarks on result'. Repeat field for each parameter cited in the study report. If the substance absorbs light at wavelengths >295 nm, give the wavelength (lambda value) of maximum absorption at wavelengths >295 nm and the maximum molar absorption (extinction) coefficient (epsilon value). If there is no absorption maximum at >295 nm, give the molar extinction coefficient at 295 nm. An alternative to the above is to attach a file that depicts graphically or in tabular form the complete UV/VIS absorption spectrum (include reference to respective Figure or Table No. in subfield 'Remarks on result').		ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.SpectrumOfSubstance
Parameter	Select parameter from drop-down list and enter the corresponding value or range with unit (unless dimensionless) in the related text field, together with any explanation if necessary, e.g. on the study group	Open list	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndD

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	<p>the result refers to. Explanations: AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration</p>		<p>discussion.SpectrumOfSubstance.Parameter</p>
Value	<p>Enter numeric value.</p>	<p>Unit measure with Open List (Decimal)</p>	<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.SpectrumOfSubstance.Value</p>
Remarks on result	<p>This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'</p>	<p>Open list with remarks (2000)</p>	<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.SpectrumOfSubstance.RemarksOnResults</p>
Spectrum of substance			
% Degradation	<p>Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.</p>		<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.</p>	<p>Check box</p>	<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.KeyResult</p>
% Degr.	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	<p>Range (Decimal)</p>	<p>ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.Degr</p>

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St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.StDev
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.SamplingTime
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Quantum yield (for direct photolysis)	Give the reaction quantum yield of the test substance (values between 0 and 1).	Decimal	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.QuantumYield
Dissipation on half-life of parent compound	Provide the half-life / DT50 or range as appropriate. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationParentCompound
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationPa

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			rentCompound.KeyResult
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationParentCompound.DT50
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationParentCompound.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DissipationParentCompound.RemarksOnResults
Dissipation half-life of parent compound			
Degradation rate constant	If provided, specify the rate constant for the reaction with OH radicals and/or ozone.		ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant.KeyResult
Reaction with	Select the type of molecule the substance reacts with from drop-down list, i.e. OH or ozone or select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant.ReactionWith

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Rate constant	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant.RateConstant
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.DegradationRateConstant.RemarksOnResults
Degradation rate constant			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'. Not relevant for microorganisms	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'. Not relevant for microorganisms		ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.IdentityTrans

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			formation.ReferenceSubstance
Identity of transformation products			
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.ResultsReferenceSubstance
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ApplicantSummaryAndConclusion

7.3.2 Transport via air - Endpoint study record

Purpose:

Chemical active substance: If the trigger for volatilisation, $V_p = 10^{-5}$ Pa (plant) or 10^{-4} Pa (soil) at a temperature of 20 °C, is exceeded and (drift) mitigation measures are required, data from confined experiments may be reported.

Chemical product: Where relevant, laboratory, wind-tunnel or field experiments to determine PECS from deposition following volatilisation and mitigation measures shall be provided.

If needed, experiments to determine deposition following volatilisation may be provided.

The national competent authorities shall be consulted to decide whether this information is necessary.

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ENDPOINT_STUDY_RECORD.TransportViaAir v1.2 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.TransportViaAir.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.TransportViaAir.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.TransportViaAir.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.TransportViaAir.ApplicantSummaryAndConclusion

Links to support material:

Pesticides in Air: Considerations for Exposure Assessment”. Report of the FOCUS Working Group on Pesticides in Air (SANCO/10553/2006 Rev 2 June 2008)

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7.3.3 Local and global effects - Endpoint summary

Purpose

Provide summary information on the local and global effects for substances that are applied in high amounts, and than global warming potential, ozone depleting potential, photochemical ozone creation potential, accumulation in the troposphere, acidification potential, eutrophication potential shall be considered.

ENDPOINT_SUMMARY.AdditionalInformationOnEnvironmentalFateAndBehaviour v.3.0			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block Conclude on the Persistence and multiplication (competitiveness) in soil, water and air	Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnEnvironmentalFateAndBehaviour.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnEnvironmentalFateAndBehaviour.Discussion

7.3.3 Local and global effects - Endpoint study record

Purpose

Provide appropriate information on the local and global effects for substances that are applied in high amounts, and than global warming potential, ozone depleting potential, photochemical ozone creation potential, accumulation in the troposphere, acidification potential, eutrophication potential shall be considered.

ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour v.6.3			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalF

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			ateAndBehaviour.DataS ource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RE CORD.AdditionalInform ationOnEnvironmentalF ateAndBehaviour.DataS ource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RE CORD.AdditionalInform ationOnEnvironmentalF ateAndBehaviour.Materi alsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RE CORD.AdditionalInform ationOnEnvironmentalF ateAndBehaviour.Materi alsAndMethods.TestMat erials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RE CORD.AdditionalInform ationOnEnvironmentalF ateAndBehaviour.Materi alsAndMethods.TestMat erials.TestMaterialInfor mation
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RE CORD.AdditionalInform ationOnEnvironmentalF ateAndBehaviour.Materi alsAndMethods.AnyOth erInformationOnMateria lsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RE CORD.AdditionalInform ationOnEnvironmentalF ateAndBehaviour.Result sAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RE CORD.AdditionalInform ationOnEnvironmentalF ateAndBehaviour.Result sAndDiscussion.AnyOth erInformationOnResults InclTables

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Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour.ApplicantSummaryAndConclusion

7.4 Residue definition for risk assessment and environmental monitoring – Flexible record

Purpose:

Chemicals: Considering the results of toxicological and ecotoxicological testing, the residue for monitoring shall be defined to include those components from the definition of the residue for risk assessment, which are considered relevant when assessing the results in those tests. Report summary information on residue definition for risk assessment and monitoring relevant for each environmental compartment.

FLEXIBLE_SUMMARY.DefinitionResidueFate v1.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block The general rules on confidentiality requests apply in setting the flags (Administrative data summary – common block). See section on Confidentiality of dossiers	Header 1	FLEXIBLE_SUMMARY.DefinitionResidueFate.AdministrativeDataSummary
Definition of the residue for risk assessment	Report the risk assessment residue definitions for the different environmental compartments in this repeatable block		FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionRiskAssessment
Compartment	Select relevant compartment from the pick list (e.g. soil, surface water, etc...)	Open list with remarks	FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionRiskAs

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			essment.Compartment
Residue definition risk assessment	Enter the residue definition for risk assessment for the selected compartment.	Multi-line text	FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionRiskAssessment.ResidueDefinitionRisk
Residue definition risk assessment components	Link to the reference substances included in the residue definition.	Entity reference list	FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionRiskAssessment.ResidueDefinitionRiskComp
Definition of the residue for risk assessment			
Definition of the residue for monitoring	Report the monitoring residue definitions for the different environmental compartments in this repeatable block		FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionMonitoring
Compartment	Select relevant compartment from the pick list e.g. soil or surface water	Open list with remarks	FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionMonitoring.Compartment
Residue definition monitoring	Enter the residue definition for risk assessment for the selected compartment.	Multi-line text	FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionMonitoring.ResidueDefinitionMonitoring
Residue definition monitoring components	Select the reference substance(s) included in the residue definition.	Entity reference list	FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionMonit

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			oring.ResidueDefinitionMonitoringComp
Monitoring residue definition LOQ (mg/kg)	Enter the LOQ for the residue definition for monitoring and enforcement. Report the value in mg/kg.	Decimal	FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionMonitoring.MonitoringResidueDefinitionLoq
Link to validated method		Endpoint reference field	FLEXIBLE_SUMMARY.DefinitionResidueFate.KeyInformation.ResidueDefinitionMonitoring.LinkToValidatedMethod
Definition of the residue for monitoring			
Additional information	Discussion (Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.DefinitionResidueFate.Discussion

7.5 Monitoring data – Endpoint summary

Purpose:

Summary information of the most relevant findings should be reported. Evaluations of monitoring data should be reported in this document, this would include vulnerability assessment and GIS contextualization.

ENDPOINT_SUMMARY.MonitoringData v3.0 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MonitoringData.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.MonitoringData.Discussion

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7.5 Monitoring data – Endpoint study record

Purpose:

Available monitoring data concerning fate and behaviour of the active substance and relevant metabolites, breakdown and reaction products in soil, groundwater, surface water, sediment and air shall be reported.

ENDPOINT_STUDY_RECORD.MonitoringData v6.5 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MonitoringData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MonitoringData.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.MonitoringData.MaterialsAndMethods
Type of measurement	Indicate the type of measurement, i.e. background concentration, concentration at contaminated site or other.	Open list with remarks	ENDPOINT_STUDY_RECORD.MonitoringData.MaterialsAndMethods.TypeOfMeasurement
Media	Indicate the medium where the samples were taken from. If different media were examined enter the respective data in separate records.	Open list	ENDPOINT_STUDY_RECORD.MonitoringData.MaterialsAndMethods.Media
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.MonitoringData.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.MonitoringData.MaterialsAndMethods.StudyDesign
Details on sampling	Briefly describe the location and site where environmental samples were taken and include details on the sampling etc. Use freetext template and	Text template	ENDPOINT_STUDY_RECORD.MonitoringData.MaterialsAndMethods.StudyDesign.DetailsOnSampling

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	delete/add elements as appropriate. As an option you may include an excerpt from the study report.		
Details on analytical methods	Enter any details that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.MonitoringData.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.MonitoringData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion
Concentration	Enter the concentration or range of concentrations measured in above medium. In the respective subfields, indicate the country and location, whether the measurements are for the substance itself or metabolite(s) and what the period of sampling was (i.e. month/year). In the supplementary remarks field of subfield 'Substance or metabolite', the identity of a metabolite should be given if applicable. As appropriate include		ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion.Concentration

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	<p>further explanations in subfield 'Remarks', particularly state if a value entered represents the mean or median and/or include the 95 percentile. Copy this block of fields for indicating several values if necessary.</p>		
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>	Check box	ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion.Concentration.KeyResult
Country	<p>Select from drop-down list.</p>	Open list	ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion.Concentration.Country
Location	<p>Specify the location.</p>	Text	ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion.Concentration.Location
Substance or metabolite	<p>Select from drop-down list.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion.Concentration.SubstanceOrMetabolite
Conc.	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a</p>	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion.Concentration.Concentration

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	range use both numeric fields together with the appropriate qualifier(s) if applicable.		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion.Concentration.RemarksOnResults
Concentration			
Details on results	<p>Include further details on the measured concentrations as appropriate, i.e. give mean, average values and percentiles. Indicate how measurements below the LOQ and outliers were dealt with, e.g. in calculating 95th percentage values. Comprehensive data should be tabulated. As appropriate upload predefined table(s) in the rich text field 'Any other information on results incl. tables' or</p>	Multi-line text	ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion.DetailsOnResults

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	adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.MonitoringData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.MonitoringData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MonitoringData.ApplicantSummaryAndConclusion

7.6 Relevance of metabolites in ground water

Purpose:

Chemical active substance: For all metabolites, breakdown or reaction products identified as a part of the residue definition for risk assessment with respect to groundwater a PECGW calculation shall be required for assessing their relevance. Where identified metabolites, breakdown or reaction products are found to occur in concentrations above 0,1 µg/L in the leachate, an assessment of their relevance shall be required.

FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater v1.1 (Final)

Name	Instructions	Data Type	Field path
Administrative data	The general rules on confidentiality requests apply in setting the flags (Administrative data summary – common block). See section on Confidentiality of dossiers	Header 1	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.AdministrativeDataSummary.DataProtection
Link to relevant biodegradation studies	Provide link to relevant endpoint study records on biodegradation used to conclude on the occurrence	Endpoint reference list	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.AdministrativeDataSummary.RelevantBiodegradationStudies

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	of metabolites in groundwater		
Link to relevant lysimeter studies	Insert link to relevant endpoint study records on lysimeter studies used to conclude on the occurrence of metabolites in groundwater	Endpoint reference list	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.AdministrativeDataSummary.RellevantLysimeterStudies
Description of key information	See the Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC.	Header 1	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.field436
Step 1: Exclusion of degradation products of no concern	This step applies to all metabolites. A degradation product which may be expected to occur in groundwater as a result of a soil degradation study or a lysimeter study will require further assessment unless one of the following conditions apply: a) it is CO ₂ or an inorganic compound, not containing a heavy metal; or, b) it is an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and which has no "alerting structures" such as epoxide, nitrosamine, nitrile or other functional groups of known toxicological concern. c) it is a substance, which is known to be of no toxicological or ecotoxicological concern, and which is naturally occurring at much higher	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepOne

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	concentrations in the respective compartment. If condition a), b) or c) is met, the degradation product is considered to be a degradation product of no concern and no additional data are required.		
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepOne.field 8430
Step 2: Quantification of potential groundwater contamination	All metabolites not excluded in Step 1 that are found in soil degradation and/or available lysimeter or field leaching studies should in principle be characterised and identified by the notifiers to the extent that is technically feasible, as outlined above in the introductory remarks to this chapter. This is particularly the case for those metabolites which are predicted to be present in the leachate leaving the upper soil layer at an annual to triannual average flux (as defined by FOCUS5) concentration exceeding 0.1 µg/L. For these metabolites the predicted environmental concentration in groundwater needs to be estimated with the highest feasible accuracy and validity.	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepTwo
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepTwo.field 247

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<p>Stage 1 of Step 3: Screening for biological activity</p>	<p>Active substances of plant protection products are defined according to Art. 2 of the Directive on the basis of their biological activity against plants or harmful organisms (in the context of this document defined as the "biological activity"). The same criterion is used here to identify those breakdown products, which – from a regulatory perspective - should be treated in the same way as active substances with respect to groundwater protection. The goal is to identify metabolites, which have a comparable target activity as the parent active ingredient, and to deal with cases where the parent molecule is a precursor of the active substance. Efficacy testing should be focused on this question of comparing the activity against the biological target. However, for parent compounds with a known range of activities, or for a compound belonging to a totally new group, it may be necessary to test a metabolite in a more extensive screening battery. Structure-activity relationships may be considered on the basis of the mode of activity of the parent molecule (i.e. usually the active substance). In many cases for compounds belonging to a well defined group of</p>	<p>Header 2</p>	<p>FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageOneStep Three</p>
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	active substances (e.g. sulfonyl thiourea herbicides) this may already provide useful and sufficient information for the assessment of this question in the absence of experimental data.		
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageOneStepThree.field3368
Stage 2 of Step 3: Screening for genotoxicity	All metabolites that have passed step 1, step 2 and stage 1 of step 3 should be screened for their genotoxic activity by at least the following package of in vitro genotoxicity studies: Ames test, gene mutation test with mammalian cells, and chromosome aberration test. Equivocal results in in vitro studies should be substantiated by in vivo experiments. Mutagenic metabolites (any category) are considered relevant.	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageTwoStepThree
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageTwoStepThree.field957
Stage 3 of Step 3: Screening for toxicity	Stage 3 of Step 3 is aimed at the question of whether a metabolite has certain toxicological properties, which - from a regulatory perspective - qualify for considering it "relevant". A metabolite is considered "relevant" if its toxicological properties lead to a classification as toxic or very toxic (T or T+) according to Directive	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageThreeStepThree

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	67/548/EEC. Reflecting the general concept of this document, the toxicity classification of the parent active substance as determined according to Directive 67/548/EEC is used for pragmatic reasons as a starting point to focus the screening activity.		
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageThreeStepThree.field2883
Step 4: Exposure assessment - threshold of concern approach	Metabolites which have not been identified as being relevant according to the hazard screening outlined in Step 3, should be further tested in an exposure assessment to make sure that any contamination of groundwater will not lead to unacceptable exposure of consumers via their drinking water.	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepFour
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepFour.field992
Step 5: Refined risk assessments for non-relevant metabolites	Metabolites which have passed steps 1 to 3 and for which levels of estimated concentrations of metabolites in groundwater (as defined in Step 2) lie between 0.75 µg/L (from Step 4) and 10 µg/L ¹² will require a refined assessment of their potential toxicological significance for consumers. All such metabolites, which are estimated to occur at levels exceeding the toxicological threshold for	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepFive

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	unknown substances, must be fully identified and also synthesised by the notifier, if necessary to allow their further testing.		
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepFive.field 9341
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Header 1	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion
	Provide any additional information related to the endpoint.	Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion.Discussion
Attached background material	<p>Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.</p>		FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it	Single file attachment	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Dis

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	differs from the non-confidential file uploaded under "Attached (sanitised) documents for publication". If a file is uploaded under this field a confidentiality claim must be submitted for each part of the file considered confidential.		cussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.	Attachments list	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion.AttachedSanitisedDocsForPublication

Links to support material:

Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC (Guidance Sanco/221/2000 –rev.10- final)

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8 Ecotoxicological studies on the active substance - Flexible record

Purpose

This document can be used to provide an overall assessment of the ecotoxicological effects of the active substance/plant protection product on the different groups of non-target organisms (NTOs) based on the available studies.

For each group of NTOs (birds and other terrestrial vertebrates, aquatic organisms, bees and other non-target arthropods, soil macro, terrestrial non-target higher plants, and micro-organisms and organisms involved in biological sewage treatment), the outcome of the risk assessment according to the agreed guidelines should be summarised.

FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides v.1.1			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.AdministrativeDataSummary
Ecotoxicological risk assessment of pesticides	This document can be used to provide an overall assessment of the toxicological effects on non-target organisms based on the studies provided in this section.	Header 1	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides
Risk assessment to birds		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentBirds
	Provide a summary of the risk assessment to birds. A table with the toxicity:exposure ratios following the EFSA birds and mammals guidance (EFSA, 2009) can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentBirds.field9187
Risk assessment to wild mammals		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentWildMammals
	Provide a summary of the risk assessment to wild mammals. A table with the toxicity:exposure ratios following the EFSA birds and mammals guidance (EFSA, 2009) can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentWildMammals.field8618

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Risk assessment to other terrestrial vertebrates		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentOtherTerrestrialVertebrates
	Provide a summary of the risk assessment to other non-target vertebrates other than birds and mammals.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentOtherTerrestrialVertebrates.field593
Risk assessment to aquatic organisms		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentAquaticOrganisms
	Provide a summary of the risk assessment to aquatic organisms. A table with the regulatory acceptable concentrations for the relevant groups of aquatic organisms following the EFSA aquatic guidance document (EFSA, 2013) can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentAquaticOrganisms.field4291
Risk assessment to bees		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentBees
	Provide a summary of the risk assessment to bees. A table with the hazard quotients and exposure: toxicity ratios for the relevant routes of exposure can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentBees.field9185
Risk assessment to non-target arthropods other than bees		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentNonBees
	Provide a summary of the risk assessment to non-target arthropods other than bees. A table with the hazard quotients for the species tested and for the in-field and off-field scenarios following ESCORT 2 can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentNonBees.field5875

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Risk assessment to non-target soil meso- and macrofauna		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSoilMesoMacrofauna
	Provide a summary of the risk assessment to soil organisms. A table with the toxicity: exposure ratios for the relevant groups of soil organisms (earthworms, collembolans, predatory mites) following the guidance document on terrestrial ecotoxicology SANCO/10329/2002 can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSoilMesoMacrofauna.field9216
Risk assessment to soil nitrogen transformation		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSoilTransformation
	Provide a summary of the risk assessment to soil nitrogen transformation.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSoilTransformation.field9651
Risk assessment to terrestrial non-target higher plants		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentHigherPlants
	Provide a summary of the probabilistic/deterministic risk assessment to terrestrial non-target higher plants. A table with the toxicity: exposure ratios following the guidance document on terrestrial ecotoxicology SANCO/10329/2002 can be included.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentHigherPlants.field4576
Risk assessment to biological methods for sewage treatment		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSewageTreatmentMethods

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	Provide a summary of the risk assessment to microorganism involved in biological sewage treatment.	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentSewageTreatmentMethods.field6508
Risk assessment to other terrestrial organisms (flora and fauna)		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentToOtherTerrestrialOrganismsFloraAndFauna
		Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentToOtherTerrestrialOrganismsFloraAndFauna.field2441
Additional information for the ecotoxicological risk assessment of pesticides	Discussion (Header 1) – common block A document as attachment pdf/doc can be provided where the risk assessment for the different taxa is conducted according to the agreed guidelines and for addressing the EU pesticides data requirements. The original version of the document should be provided if it differs from the publication version.	Header 1	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.AdditionalInformation

8.1.1 Effects on birds (acute, short-term dietary, sub-chronic and reproductive) - Endpoint summary

<p>Purpose</p> <p>Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, including:</p> <ul style="list-style-type: none"> - Category (e.g. insectivorous bird) and species, - Time-scale, - Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects).
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ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Data type	Field path

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Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa
Short-term toxicity to birds			ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.ShortTermToxicity
Study name / type	Select the study for which the endpoint was derived.	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.ShortTermToxicity.Link
Test organisms (species)	Select the organism(s) for which the endpoint was derived.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.ShortTermToxicity.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.ShortTermToxicity.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.ShortTermToxicity.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect." In the long-term study: Select 'not specified' if the effect concentration type is not known.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.ShortTermToxicity.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed. If it is a corrected value, please indicate why.	Closed list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.ShortTermToxicity.DoseDescriptor

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Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In (mg/kg bw per day) . For micro-organisms, average achieved dose in colony forming units (cfu) also must be reported.	Range with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.ShortTermToxicity.EffectConcentration
Short-term toxicity to birds			
Long-term toxicity to birds			ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity
Study name / type	Select the study for which the endpoint was derived.	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.Link
Test organisms (species)	Select the organism(s) for which the endpoint was derived.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect."	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed. If it is a corrected value, please indicate why.	Open list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsa.LongTermToxicity.DoseDescriptor

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Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In (mg/kg bw per day). For micro-organisms, average achieved dose in colony forming units (cfu) must be reported.	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.KeyValueForCsLongTermToxicity.EffectConcentration
Long-term toxicity to birds			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa). Information concerning the residue decline in potential food items of birds can be described here. Make reference to endpoint studies used in this analysis	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PP.Discussion

8.1.1 Effects on birds (acute, short-term dietary, sub-chronic and reproductive) - Endpoint study record

Purpose

Information on toxicity, infectiveness and pathogenicity to birds must be reported.

A study shall be provided establishing the acute oral toxicity (LD₅₀) of the active substance. The study shall provide, where possible, LD₅₀ values. The lethal threshold dose, time courses of response and recovery, the LD₁₀ and LD₂₀ shall be reported together with the no observed effect level (NOEL) and gross pathological findings. Where LD₁₀ and LD₂₀ cannot be estimated, an explanation shall be provided. Study design shall be optimised for the achievement of an accurate LD₅₀.

A study shall be provided establishing the short-term dietary toxicity. LC₅₀ values, lowest lethal concentration (LLC), where possible, no observed effect concentration (NOEC) values, time courses of response and recovery and pathological findings shall be reported in such study. LC₅₀ and NOEC values shall be converted to daily dietary dose (LD₅₀) expressed in mg substance/kg bw/day and NOEL expressed in mg substance/kg bw/day.

A study shall be provided establishing the sub-chronic and reproductive toxicity of the substance to birds. The EC₁₀ and EC₂₀ shall be reported. Where they cannot be estimated, an explanation shall be provided together with the NOEC expressed in mg substance/kg bw/day.

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ENDPOINT_STUDY_RECORD.ToxicityToBirds – v.7.4 (Final) [September 2020]			
Name	Instructions	Data Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToBirds.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline No 223: Avian acute oral toxicity study OECD Test Guideline No 223: Avian acute oral toxicity study (updated version of July 2016) US EPA OCSPP 850.2100: Avian oral toxicity test OECD Test Guideline 205: Avian Dietary Toxicity Test US EPA OCSPP 850.2200: Avian dietary toxicity test. OECD Test Guideline 206: Avian Reproduction Test US EPA OCSPP 850.2300: Avian Reproduction Test OPPTS 885.4050 Avian Oral, Tier I OPPTS 885.4600 Avian Chronic Pathogenicity and Reproduction Test, Tier III	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.

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			MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterialInformation
Dose method	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.DoseMethod
Analytical monitoring	Indicate whether test substance was monitored in the test medium. If yes, specify in field 'Details on preparation and monitoring of diet'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.AnalyticalMonitoring
Vehicle	Indicate whether a vehicle was used, e.g. to disperse/solubilise or facilitate mixing of test substance with feed.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.Vehicle
Details on preparation and analysis of diet	Indicate whether a vehicle was used, e.g. to disperse/solubilise or facilitate mixing of test substance with feed. Indicate details about diet preparation and homogeneity analysis of test material. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. In the case of OECD or similarly acknowledged guideline only items may be covered where deviations apply or where parameters are left open in the	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.DetailsOnPreparationAndAnalysisOfDiet

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	guideline, provided the respective regulatory programme allows so.		
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestOrganisms
Test organisms (species)	Select the species from the picklist. If not available, select 'other' and enter the species name of the test organism.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Details on test organisms	Enter any details that could be relevant for evaluating this study summary. Use free-text template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms
Study design		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.LimitTest
Total exposure duration (if not single dose)	Select from drop-down list.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.TotalExposureDuration
Remarks	Enter any remarks related to the total exposure duration.	Text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.Remarks
Post exposure observation period	Indicate the post-observation period (with unit) during which 'clean' feed was administered.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.PostExposureObservationPeriod

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<p>No. of animals per sex per dose and/or stage</p>	<p>Indicate the post-observation period (with unit) during which 'clean' feed was administered. Indicate number of animals used per dose group and/or stage. State if different numbers were used and reason why.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.NoOfAnimalsPerSexPerDose</p>
<p>Control animals</p>	<p>Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.</p>	<p>Multi select open list with remarks</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.ControlAnimals</p>
<p>Nominal and measured doses / concentrations</p>	<p>List nominal and, if available, measured dose levels or test concentrations (with unit). Indicate if nominal or measured for bolus dose, etc. Provide range, median, mean, SD as applicable. As appropriate tabulate nominal vs. measured concentrations and refer to Table no.</p> <p>For micro-organisms, average achieved dose in colony forming units (cfu) also must be reported.</p>	<p>Multi-line text</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.NominalAndMeasuredDosesConcentrations</p>
<p>Details on test conditions</p>	<p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or</p>	<p>Text template</p>	<p>ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions</p>

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	that are requested by the respective regulatory programme.		
Examinations		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Examinations
Details on examinations and observations	Indicate the time schedule and further details for all examinations and observations performed (use separate free-text field for reproductive parameters, if applicable). Also indicate the dose groups that were examined if not all. When tabulating parameters examined, refer to respective table no. Use free-text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Examinations.DetailsOnExaminationsAndObservations
Details on reproductive parameters	For avian reproduction toxicity test, indicate the reproductive parameters examined. Use free-text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Examinations.DetailsOnReproductiveParameters

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	the respective regulatory programme.		
Reference substance (positive control)	Indicate if a positive control was tested, i.e. a reference substance with known toxicity. If yes, include the identity of the substance(s) and the concentrations in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Examinations.ReferenceSubstancePositiveControl
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion
Effect levels	Report the LC50, LD50, NOEC or LOEC for appropriate parental and reproductive parameters depending on the study type. Copy this field block for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.KeyResult
Duration (if not single dose)	Enter numeric value (not relevant for bolus dose) and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.Endpoint

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	quantified level of effects.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.EffectLevel
Conc. / dose based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.ConcDoseBasedOn
Basis for effect	Select effect parameter such as mortality, which the effect concentration relates to. As appropriate	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.BasisForEffect

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	include further details in the supplementary remarks field, e.g. 'related to number of eggs or young surviving'.		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Repellency factors (if applicable)	If repellency was investigated, describe the repellency results including all repellency factors (RF) given in the study report, i.e. either for each bird (choice test) or for per test group (no-choice test). As appropriate include or attach a table.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.RepellencyFactors
Mortality and sub-lethal effects	Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.MortalityAndSubLethalEffects

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	<p>an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.</p>		
Effects on reproduction	<p>For avian reproduction toxicity test, include data on reproduction during pre-treatment and treatment periods depending on the requirements of the test guideline used. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectsOnReproduction

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	Note: Specific tables may be required.		
Results with reference substance (positive control)	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.ResultsWithReferenceSubstance
Further details on results	For microbial organisms, information on infectiveness and pathogenicity to birds must be reported.	Text area	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.FurtherDetailsOnResults
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.ReportedStatisticsAndErrorEstimates
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ApplicantSummaryAndConclusion

Links to support materials

OECD series of testing and assessment Number 54. "Current approaches in the statistical analysis of ecotoxicity data: a guidance to application"

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2006\)18&docLanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2006)18&docLanguage=en)

EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438.

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8.1.2 Effects on terrestrial vertebrates other than birds – Endpoint summary

Purpose:

Summarise the most relevant information from the available relevant acute and long-term study(-ies) derived from the mammalian toxicological assessment.

This information could include, for instance:

The test guideline used;

The test organism tested;

The exposure duration;

The results obtained.

ENDPOINT_SUMMARY.TerrestrialToxicity v5.0 (Final) [July 2020]

Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.TerrestrialToxicity.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.TerrestrialToxicity.Discussion

Links to support material:

EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. <https://doi.org/10.2903/j.efsa.2009.1438>

8.1.3 Effects of active substance bioconcentration in prey of birds and mammals

Purpose:

Chemicals active substance: Conclude on the available and relevant data, including data from the open literature for the active substance of concern, regarding the potential effects to birds, mammals, reptiles and amphibians.

Chemicals product: Where it cannot be predicted from the active substance data and, if relevant, conclude on the risk to amphibians and reptiles from plant protection products considering the submitted endpoint studies

ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP v1.3 (Final)

Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.AdministrativeDataSummary

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Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa
Short-term toxicity to other above-ground organisms (wild mammals)			ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther
Study name / type		Endpoint reference field	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.Link
Test organisms (species)	Select the organism(s) for which the endpoint was derived. Select 'not specified' if the effect concentration type is not known.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.TestOrganismsSpecies
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.ParentMetabolite
Substance	Select the test substance.	Entity reference field	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed.	Closed list	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.ShortTermToxicityOther.EffectConcentration

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	is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable.		
Short-term toxicity to other above-ground organisms (wild mammals)			
Long-term toxicity to other above-ground organisms (wild mammals)			ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther
Study name / type		Endpoint reference field	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.Link
Test organisms (species)	Select the organism(s) for which the endpoint was derived.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.TestOrganismsSpecies
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.ParentMetabolite
Substance	Select the test substance.	Entity reference field	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.Substance
Basis for effect	Select the type of effect for the endpoint setting (e.g. mortality, reproduction, behaviour, etc.).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed.	Open list	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.KeyValueForCsa.LongTermToxicityOther.EffectConcentration

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	no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable.		
Long-term toxicity to other above-ground organisms (wild mammals)			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP.Discussion

Links to support material

EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438.

OECD series of testing and assessment Number 54. "Current approaches in the statistical analysis of ecotoxicity data: a guidance to application"

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)

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8.1.3 Effects of active substance bioconcentration in prey of birds and mammals - Endpoint study record

Purpose:

Microorganisms: Any available information on the effects on non-target organisms within the area to which the micro-organism may spread shall be given. The occurrence of non-target organisms being either closely related to the target species or being especially exposed shall be indicated.

Any experience of the toxic effect of the active substance or its metabolic products on humans or animals, of whether the organism is capable of colonising or invading humans or animals (including immunosuppressed individuals) and whether it is pathogenic shall be stated. Any experience of whether the active substance or its products may irritate skin, eyes or respiratory organs of humans or animals and whether it is allergenic in contact with skin or when inhaled shall be stated.

Chemicals: Higher tier studies on mammals shall be conducted where the first tiers of the risk assessment do not demonstrate that risk is acceptable

Where it cannot be predicted from the active substance data and, if relevant, the risk to amphibians and reptiles from plant protection products shall be addressed. The type and conditions of the studies to be provided shall be discussed with the national competent authorities.

ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms v.6.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.TestMaterials.TestMaterialInformation

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Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.StudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms.ApplicantSummaryAndConclusion

8.2 Effects on aquatic organisms – Flexible summary

Purpose:

Regulatory acceptable concentration (RAC) values estimated dividing the derived endpoints by the corresponding assessment factor should be reported for the relevant groups of aquatic organisms (fish, aquatic invertebrates, algae, sediment-dwellers, macrophytes) following the EFSA aquatic guidance document (EFSA, 2013).

FLEXIBLE_SUMMARY.AquaticToxicityRacReporting v1.1 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.AdministrativeDataSummary
RAC values	Report the RAC values according to the EFSA, 2013.		FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues
Parent / metabolite	Specify whether the RAC refers to the	Closed list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.ParentMetabolite

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	parent or to a metabolite.		
Substance	Specify the name of the active substance or metabolite to which the information refers to.	Entity reference field	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.Substance
Test organisms	Select the relevant aquatic organism group to which the information refers.	Multi select open list with remarks	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.TestOrganisms
Time scale	Select the time scale for the risk assessment.	Closed list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.TimeScale
Tier	Select the tier for the risk assessment.	Closed list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.Tier
Assessment factor	Select the assessment factor for the risk assessment.	Multi select open list with remarks	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.AssessmentFactor
Type of RAC value	Select the type of RAC derived.	Closed list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.RacValueType
RAC value	Include the RAC value and the pertinent units.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.KeyInformation.RACValues.RacValue
RAC values			
Additional information	Provide additional information related to the RAC derivation that was not possible to capture in previous fields.	Header 1	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion
		Rich text area	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.Discussion
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.		FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.AttachedBackgroundMaterial

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Attached document	Provide any additional documents relevant for the submission.	Single file attachment	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	If required, an electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. These attachments should be sanitised if needed.	Attachments list	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting.Discussion.AttachedSanitisedDocsForPublication

Links to support material:

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. <https://doi.org/10.2903/j.efsa.2013.3290>

8.2.1 Acute toxicity to fish- Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details:

- Group: Specify Fish species;
- Time scale;
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects).

ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP – v.1.3 (Final) [October 2020]

Name	Instructions	Data type	Field path
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Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment	Section for reporting of tier 1 studies.	Header 1	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa
Short-term toxicity to freshwater fish			ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwaterFish
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwaterFish.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwaterFish.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwaterFish.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwaterFish.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint	Closed list	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.S

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	assessed (EC50, LC50 or NOEC).		hortTermToxicityFresh waterFish.DoseDescript or
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range, use both numeric fields together with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFresh waterFish.EffectConcentration
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Open list	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFresh waterFish.NominalMeasured
Short-term toxicity to freshwater fish			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.Discussion

Links to support materials

OECD. Series on testing and assessment No 126. Short guidance on the threshold approach for acute fish toxicity. ENV/JM/MONO(2010)17

<https://ntp.niehs.nih.gov/iccvam/suppdocs/feddocs/oced/oced-gd126.pdf>

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8.2.1 Acute toxicity to fish - Endpoint study record

Purpose

A study shall be provided on the acute toxicity to fish (LC₅₀) and details of observed effects. Information on toxicity, infectiveness and pathogenicity to fish must be reported

ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish – v. 6.5 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 203: Fish, Acute Toxicity Test EPA OPPTS 885.4200 - Freshwater Fish Testing, Tier I (February 1996)	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.StudyDesign

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Test conditions	Test conditions block In the “nominal and measured concentrations” field, the average achieved dose in cfu must be reported.	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentrations.EffectConc

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Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Close list	ENDPOINT_STUDY_RESULT.ToFish.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RESULT.ToFish.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	For acute fish test, select effect parameter such as mortality or visible abnormalities related to appearance and behaviour. As appropriate include further details in the supplementary remarks field. For fish embryo test, select indicators of mortality (or lethality): (i) coagulation of fertilised eggs, (ii) lack of somite formation, (iii) lack of detachment of the tailbud from the yolk sac, and (iv) lack of heartbeat. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RESULT.ToFish.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.	Open list with remarks (2000)	ENDPOINT_STUDY_RESULT.ToFish.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults

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Effect concentrations			
Details on results	Information on toxicity, infectiveness and pathogenicity to fish must be reported.	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.ResultsDetails
Results with reference substance (positive control)	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Sublethal observations / clinical signs	<p>In this field, you can enter any other remarks on results or observations e.g. sub lethal effects recorded during the study. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.</p> <p>Optionally include clinical signs, using predefined (or other) table as proposed in TG 203, Annex 4.</p> <p>Percentages of test animals that showed symptomology.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS</p>	Rich text area	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.SublethalObservationsClinicalSigns

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	section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.		
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ApplicantSummaryAndConclusion

8.2.2.1 Long-term and chronic toxicity to fish – Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details:</p> <ul style="list-style-type: none"> - Group: Specify fish species - Time scale - Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
--

ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP – v.1.4 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment	Section specific for reporting of tier 1 studies.	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment
Long-term toxicity to freshwater fish			ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish
Test organism	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.K

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ms (species)		open list with remarks	eyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed. If it is a corrected value, please indicate why.	Closed list	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable.	Range with closed list (Decimal)	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Open list	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxFreshwaterFish.NominalMeasured
Long-term toxicity to freshwater fish			

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EC10, LC10 or NOEC for marine water fish	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	Range with closed list (Decimal)	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAssessment.EcTenLcTenNoecMarineWaterFish
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.Discussion

8.2.2.1 Long-term and chronic toxicity to fish - Endpoint study record

<p>Purpose</p> <p>A long-term or chronic toxicity study on fish shall be provided for all active substances where exposure of surface water is likely and the substance is deemed to be stable in water, that is to say there is less than 90 % loss of the original substance over 24 hours via hydrolysis (see point 7.2.1.1). A fish early life stage study shall be provided in these circumstances. However, if a fish full life cycle study is provided an early life stage study shall not be required.</p> <p>Information on toxicity, infectiveness and pathogenicity to fish must be reported.</p>

ENDPOINT_STUDY_RECORD.LongTermToxToFish – v.6.5 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxToFish.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxToFish.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.LongTermToxToFish.DataSource.Reference

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Materials and methods	Material and methods – common block Applicable test guidelines: OPPTS 885.4700 Fish Life Cycle Studies, Tier III OECD Test Guideline 210: Fish, Early-Life Stage Toxicity Test US EPA protocol OCSP 850.1500 Fish life cycle toxicity Are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds.TestMaterials.TestM aterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds.TestOrganisms
Test organisms (species)	Select the name of the species. If not available, select 'other' and specify.	Open list	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds.TestOrganisms.Test OrganismsSpecies
Details on test organisms	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by	Text template	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds.TestOrganisms.Detai lsOnTestOrganisms

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	the respective regulatory programme.		
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds.StudyDesign
Test conditions	Test conditions block Nominal and measured concentrations: Actual achieved dose in colony forming must be reported.	Header 2	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.MaterialsAndMetho ds.AnyOtherInformatio nOnMaterialsAndMetho dsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.) Details on results: Information on toxicity, infectiveness and pathogenicity to fish must be reported Isolation, identification, and enumeration of microorganisms responsible for any observed pathogenic effects.	Header 1	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.ResultsAndDiscussi on
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.ResultsAndDiscussi on.AnyOtherInformatio nOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.OverallRemarksAtt achments

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Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RE CORD.LongTermToxTo Fish.ApplicantSummary AndConclusion
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8.2.2.2 Bioconcentration in fish – Endpoint summary

<p>Purpose: Chemical: Conclude on the bioaccumulative potential of the active substance or product. Derivation of bioconcentration factors, clearance time and nature of residues from the submitted endpoint studies.</p>

ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP v1.2 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.AdministrativeDataSummary
Key value for safety assessment		Header 1	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa
Bioconcentration in fish			ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.ParentMetabolite
Substance		Entity reference field	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.Substance
logPo/w	Indicate the value for logPo/w and the pH of the substance when measured.	Text	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.LogPow
BCF (aquatic species)	Indicate the value of BCF in total wet weight/normalised to 5% lipid content and the tissue where it was measured (e.g. whole fish, edible tissue, non-edible tissue).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.BcfAquaticSpecies

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	Specify further information such as kinetic, steady state, growth corrected; whether the BCF is based on total radioactive residue or parent substance in the remark field.		
Clearance time CT50	Indicate the clearance times in days (d) (CT50). In case the clearance takes place in less than a day (e.g. 22 hr), indicate the hours (h).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.CtFiftyClearanceTime
Clearance time CT90	Indicate the clearance times in days (d) (CT900). In case the clearance takes place in less than a day (e.g. 22 hr), indicate the hours (h).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.CtNinetyClearanceTime
Nature and level of residues	Indicate the level and nature of residues (%) in organisms after the 14-day depuration phase.	Rich text area	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.NatureAndLevelOfResidues
Remarks		Text area	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.BioconcentrationFish.Remarks
Bioconcentration in fish			
BMF in fish (dimensionless)	Report the biomagnification (BMF) factor in fish as the relative concentration (lipid normalised) in a predatory animal compared with the concentration in its prey (BMF = Cpredator/Cprey).	Decimal	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.KeyValueCsa.FishBmf
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP.Discussion

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8.2.2.2 Bioconcentration in fish – Endpoint study record

Purpose:

The bioconcentration in fish of purified active substance shall be determined and the steady-state bioconcentration factors, uptake rate constants and depuration rate constants, incomplete excretion, metabolites formed in fish and, if available, information on organ-specific accumulation shall be reported.

Bioconcentration factors shall be expressed as a function of both total wet weight and of the lipid content of the fish.

Especially tests shall be provided for substances:

- with log KOW > 3
 - if there are other indications of bioconcentration
- considered stable (< 90% loss of the original substance via hydrolysis over 24 h)

ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment v.7.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.DataSource
Materials and methods	Material and methods – common block Applicable Test guideline: EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4)	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled	Closed list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestMaterials.Radiolabelling

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	material to be described in field 'Details on test material'.		
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestOrganisms
Test organisms (species)	Select species from picklist. If not available, select 'other' and enter name of organism (species).	Open list	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Details on test organisms	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

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Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion
Lipid content	Indicate the lipid content of test organisms with unit. If appropriate specify the time point at which the measurement was made, e.g. start or end of experiment. Copy this block of fields if measuring lipid content at end of uptake and end of depuration phases. Copy this block of fields for specifying the lipid content ratio in % if required.		ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.LipidContent
Lipid content	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.LipidContent.LipidContent
Time point	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.LipidContent.TimePoint

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	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'. 	<p>Open list with remarks (2000)</p>	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.LipidContent.RemarksOnResults</p>
Lipid content			
<p>Bioaccumulation factor</p>	<p>This repeatable block of fields allows reporting of the aqueous bioconcentration factors, i.e. the steady-state BCFs and/or the kinetic BCFk. For sediment-dwelling organisms BAF (bioaccumulation factor), BSAF (biota-sediment accumulation factor) and/or pore water BCFs can be specified. Also dietary</p>		<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.BioaccumulationFactor</p>

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	<p>biomagnifications factors (BMF), e.g. from fish dietary studies, can be recorded.</p> <p>For dietary biomagnification factor (dietary BMF) according to the OECD 305 part III test, the calculated assimilation efficiency (α) should also be stated.</p> <p>As appropriate or requested by the regulatory programme include table(s) in the rich text field 'Any other information on results incl. tables' showing the bioaccumulation/ bioconcentration factors measured at different time points and concentrations in the water. Upload predefined or other appropriate table(s) if any, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p>		
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Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result.sAndDiscussion.BioaccumulationFactor.KeyResult
Conc. / dose	Give the concentration in surrounding water (and/or sediment, if sediment study) or the dose level applied (if feeding study). If more than one concentration or dose was tested for which different bioaccumulation factors are reported, e.g. for high and low concentration levels, multiply this block of fields.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result.sAndDiscussion.BioaccumulationFactor.ConcInEnvironmentDose
Temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result.sAndDiscussion.BioaccumulationFactor.Temp

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	is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
pH	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.BioaccumulationFactor.Ph
Type	Indicate the reported bioaccumulation value, i.e. either BCF (bioconcentration factor which accounts for substance intake from the surrounding water or pore water if sediment study only), BAF (bioaccumulation factor which accounts for substance intake from both food and surrounding water/sediment), BSAF (biota-sediment accumulation factor), BMF (dietary biomagnification factor, i.e. the ratio between the relative concentration in a predatory animal	Open list	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.BioaccumulationFactor.Type

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	and the concentration in (part of) its prey or the kinetically derived value) or other (to be specified).		
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.BioaccumulationFactor.Value
Basis	From drop-down list, select the basis for the bioaccumulation value, i.e. expressed in relation to the whole body, the total lipid content or specific tissues of the test organisms (w.w. = wet weight; d.w. = dry weight). Note: For OECD TG 305-III dietary method, the result is reported relative to the ratio of fish lipid: food lipid.	Open list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.BioaccumulationFactor.Basis

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Time of plateau	If applicable, indicate time at which plateau was reached (for tissue concentration).	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.BioaccumulationFactor.TimeOfPlateau
Calculation basis	If the Bioaccumulation value was not calculated at steady state, select 'kinetic:' and briefly specify using the supplementary remarks field (e.g. 'kinetic: steady state at 80% of equilibrium' or, for the dietary exposure OECD 305 method, the values of assimilation efficiency, fish concentration at end of depuration etc used in the calculations).	Open list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.BioaccumulationFactor.CalculationBasis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.BioaccumulationFactor.RemarksOnResults

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	<p>explanation in the supplementary remarks field; or</p> <ul style="list-style-type: none"> - entering any additional information by selecting 'other:', e.g. for indicating if bioconcentration / bioaccumulation is based on parent compound instead of radioactivity. 		
Bioaccumulation factor			
Depuration	<p>Indicate if clearance of test substance or metabolites from test organisms was observed; give depuration time required for clearance of 50% (DT50), 90% (DT90) and or any other percent of residues.</p>		<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.Depuration</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or</p>	<p>Check box</p>	<p>ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.Result sAndDiscussion.Depuration.KeyResult</p>

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	EU REACH) on how to use this field.		
Elimination	Indicate whether elimination of test substance or metabolites occurred or not.	Closed list	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration.Elimination
Parameter	Indicate to which endpoint type the effect concentration refers, e.g. DT50.	Open list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration.Endpoint
Depuration time (DT)	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration.DepurationTime
Remarks on result Depuration	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Depuration.RemarksOnResults
Rate constants	Provide the numeric values of relevant rate constants as		ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.RateConstants

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	appropriate and/or give an explanation in field 'Explanation of result'.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.ResultsAndDiscussion.RateConstants.Key Result
Rate constant	Select the rate constant, e.g. 'growth rate constant (d-1)'. Additional free text explanation can be entered in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.ResultsAndDiscussion.RateConstants.RateConstant
Value	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.ResultsAndDiscussion.RateConstants.Value
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived;	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.ResultsAndDiscussion.RateConstants.RemarksOnResults

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	<ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'. 		
Rate constants			
Details on kinetic parameters	Give values (including 95 % confidence limits and standard deviations) for the uptake and depuration rate constants (all expressed in relation to whole body, total lipid content or specific tissues of the test organisms); give relevant details on computation/data analysis.	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.KineticParameters
Metabolites	If identified, include table(s) in the rich text field 'Any other information on results incl. tables' with data on any metabolites of the test substance accumulated in test organisms (total) and specific tissues	Text area	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.Metabolites

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	<p>thereof (e.g. lipid) (at least those, accounting for > 10 % of residues). Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p>		
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.ResultsWithReferenceSubstance
Details on results	<p>Report any other relevant results using freetext template as appropriate. Indicate any results related to the chemical properties of the test material. Compare the results for the test substance with that for the reference substance. Upload predefined or other appropriate tables(s) if any, and tailor it/them to your needs.</p>	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.DetailsOnResults
Reported statistics	<p>Indicate the parameters analysed, the</p>	Multi-line text	ENDPOINT_STUDY_RECORD.BioaccumulationAquaticSediment.ResultsAndDiscussion.ReportedStatistics

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	statistical method used and the statistical test performed.		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.Result sAndDiscussion.AnyOtherInformati onOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.Overal lRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.Applic antSummaryAndConclusion
Validity criteria fulfilled	<p>State whether validity criteria in the test guideline have been fulfilled or not. Use supplementary remarks field to state the criteria and supporting information.</p> <p>Clearly indicate if the criteria used are not consistent with those given by the test guideline. If so, give justification in field 'Rationale for reliability incl. deficiencies' as to why this study summary is considered reliable.</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.Bioac cumulationAquaticSediment.Applic antSummaryAndConclusion.Validity CriteriaFulfilled

8.2.3 Endocrine disrupting properties – Endpoint study record

Purpose:

Summarise the most relevant study results from which the key value for chemical safety assessment is extrapolated.

Provide only the most relevant details whether the active substance is a potential endocrine disruptor in aquatic nontarget organisms according to agreed guidelines, which may be:

indication of endocrine activity in fish: vitellogenin and secondary sexual characteristics (OECD No. 229 & 230 & 240)

screening of oestrogenic and androgenic activity, and aromatase inhibition in fish (OECD No. 230 & 148) effects on the thyroid system (OECD No.231)

effects on oestrogen, androgen or thyroid-mediated physiological processes in amphibian species (OECD No.241)

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ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua v4.5 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.DataSource
Materials and methods	Material and methods – common block Applicable Test guidelines: - Workshop report on OECD countries activities regarding testing, assessment and management of endocrine disrupters. Series on testing and assessment No 118. 18 January 2010.	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods

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	<ul style="list-style-type: none"> - OECD Test Guideline 229: Fish Short Term Reproduction Assay - OECD Test Guideline 230: 21-day Fish Assay: A Short-Term Screening for Oestrogenic and Androgenic Activity, and Aromatase Inhibition - OECD Test Guideline 231: Amphibian Metamorphosis Assay - OECD Test Guideline 240: Medaka Extended One-Generation Reproduction Test - Method C.52 Medaka Extended One Generation Reproduction Test (MEOGRT) (Annex of Regulation (EC) No 440/2008, as amended by the 8th ATP) - OECD Test Guideline 241: Larval Amphibian Growth and Development Test - Method C.53 The Larval Amphibian Growth and Development Assay (LAGDA) (Annex of Regulation (EC) No 440/2008, as 		
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	<p>amended by the 8th ATP</p> <ul style="list-style-type: none"> - OECD Guidance Document 148: Guidance Document on the Androgenised Female Stickleback Screen (Series on Testing and Assessment, ENV/JM/MONO(2011)29, updated version of August 2017) - OECD Series on Testing and Assessment: No 150: Guidance document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption. ENV/JM/MONO(2012)22, 524 pp - US EPA protocol OCSP 850.1500 Fish life cycle toxicity - OECD Test Guideline XXX (placeholder) EASZY assay: Detection of substances acting through estrogen receptors using transgenic cyp19a1b GFP 5643 zebrafish embryos (draft OECD TG) - OECD Test Guideline XXX (placeholder) Juvenile Medaka anti- 		
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	<p>androgen screening assay (JMASA)</p> <ul style="list-style-type: none"> - OECD Test Guideline XXX (place holder): - Rapid androgen disruption adverse outcome reporter assay (RADAR) - OECD Test Guideline XXX (place holder): Xenopus embryonic thyroid signalling assay XETA <p>Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009</p>		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestMaterials
Sampling and analysis		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.SamplingAndAnalysis
Analytical monitoring	<p>Indicate whether test substance was monitored in the test solutions or suspensions. For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.SamplingAndAnalysis.AnalyticalMonitoring

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	in the corresponding freetext fields.		
Details on sampling	If the concentration of test material was monitored, enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnSampling
Details on analytical methods	If the concentration of test material was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) for the different matrices as appropriate.	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnAnalyticalMethods
Test solutions		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestSolutions
Vehicle	Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility. If yes, specify in field 'Details on test solution'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestSolutions.Vehicle
Details on test solutions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestSolutions.DetailsOnTestSolutions

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	<p>summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.</p> <p>If a solvent control is included, detail whether a dilution water (procedural) control was also included or omitted.</p>		
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestOrganisms
Aquatic vertebrate type	Select type of aquatic vertebrate from picklist. If not available, select 'other' and type name of aquatic vertebrate.	Open list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestOrganisms.AquaticVertebrateType
Test organisms (species)	Select the name of the species or type of activated sludge used as inoculum. If not available, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Details on test organisms	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms

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	respective regulatory programme.		
Study design		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.StudyDesign
Test type	Select appropriate test type.	Open list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.StudyDesign.TestType
Water media type	Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine or other water.	Open list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.StudyDesign.WaterMediaType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.StudyDesign.LimitTest
Total exposure duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.StudyDesign.TotalExposureDuration
Remarks on exposure duration	Enter any remarks related to the total exposure duration.	Text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.StudyDesign.RemarksOnExposureDuration
Post exposure observation period	Indicate the post-observation period if appropriate.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.StudyDesign.PostExposureObservationPeriod
Test conditions		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestConditions
Hardness	Indicate water hardness as mg/L calcium carbonate equivalent values measured in the	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestConditions.Hardness

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	<p>treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.</p>		
Test temperature	<p>Indicate test temperature values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. As appropriate state the location (e.g. water bath, test chambers) and type of measurement (e.g. continuous monitoring). Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestConditions.Test Temperature
pH	<p>Indicate pH values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Indicate how mean pH is to be obtained.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestConditions.Ph

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	Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.		
Dissolved oxygen	Indicate dissolved oxygen values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestConditions.DissolvedOxygen
Salinity	For marine studies, indicate salinity (if relevant) values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestConditions.Salinity
Conductivity	Indicate conductivity values measured in the treatment and control solutions during test. Include range, mean,	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestConditions.Conductivity

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	<p>standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.</p>		
Nominal and measured concentrations	<p>List nominal and, if available, measured test concentrations used in the study. As appropriate tabulate nominal vs. measured concentrations in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available any, and tailor it/them to your needs or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded. Note: Specific tables may be required.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestConditions.NominalAndMeasuredConcentrations
Details on test conditions	<p>Select freetext template for the respective type of</p>	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMe

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	study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		thods.TestConditions.DetailsOnTestConditions
Reference substance (positive control)	Indicate if a positive control was tested, i.e. a reference substance with known toxicity. If yes, include the identity of the substance(s) (e.g. 3,5-dichlorophenol, copper(II) sulfate pentahydrate, other) and the concentrations in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.TestConditions.ReferenceSubstancePositiveControl
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key	Check box	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTest

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	information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.		ingInAqua.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time	Closed list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.EffectConcentrations.NominalMeasured

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	weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.		
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates	Open list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.EffectConcentrations.BasisForEffect

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	to. As appropriate include further details in the supplementary remarks field.		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults

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	determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.		
Effect concentrations			
Details on results	<p>Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Particularly with comprehensive data, include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Narrative accompanying such tabular data can then be rather short and should not repeat what is presented in the table(s). The same holds true if any</p>	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.ResultsDetails

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	figure is attached in field 'Attached background material'. Note: Specific tables may be required.		
Results with reference substance (positive control)	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterTestingInAqua.ApplicantSummaryAndConclusion

Links to support material:

Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 428/2012 and (EC) No 1107/2009. <https://www.efsa.europa.eu/en/efsajournal/pub/5311>

8.2.4 Acute toxicity to aquatic invertebrates - Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g.:

- Group: Specify Invertebrate species;
- Time scale;
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)

ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa
Short-term toxicity to aquatic invertebrates			ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates

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Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.TestOrganismsSpecies
Parent / metabolite	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Closed list	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.ParentMetabolite
Substance	Indicate whether the endpoint is for the active substance or a metabolite	Entity reference field	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (EC50 or LC50).	Closed list	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.EffectConcentration
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Open list	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.ShortTermToxAquaInvertebrates.NominalMeasured
Short-term toxicity to aquatic			

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invertebrates			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.Discussion

Links to support material:

Guidance Document on Tiered Risk Assessment for Plant Protection products for Aquatic Organisms in Edge-of-field Surface Waters in the Context of Regulation (EC) No 1107/2009 (SANTE-2015-00080, 15 January 2015) https://www.efsa.europa.eu/en/efsajournal/pub/3290_10.2903/j.efsa.2013.3290

8.2.4 Acute toxicity to aquatic invertebrates - Endpoint study record

Purpose

The acute toxicity shall be determined for a *Daphnia* species (preferably *Daphnia magna*). For active substances with an insecticidal mode of action or which show insecticidal activity a second species shall be tested, for example Chironomid larvae or Mysid shrimps (*Americamysis bahia*). A test shall be provided on the 24- and 48-hour acute toxicity of the active substance to *Daphnia magna*, expressed as the median effective concentration (EC₅₀) for immobilisation, and where possible, the highest concentration causing no immobilisation.

Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.

ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv – v.7.4 (Final) [September 2020]

Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermTo

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			xicityToAquaInv.Data Source
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.Data Source.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 202: <i>Daphnia sp.</i> Acute Immobilisation Test US EPA OCSPP 850.1035 Mysid Acute Toxicity Test OECD Test Guideline 235: <i>Chironomus sp.</i> , Acute Immobilisation Test OPPTS 885.4240 Freshwater Aquatic Invertebrate Testing, Tier I	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.Test Materials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.Test Materials.TestMaterial Information
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block Nominal and measured concentrations: Actual achieved dose in colony forming units must be reported.	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.Test Conditions
Any other information	Any other information on materials and methods incl. tables - (H2) – common block A detailed description of the steps taken to determine microorganism dissemination,	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.Any

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materials and methods incl. tables	replication, or survival in the test animal tissues, organs, or fluids.		OtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.NominalMeasured

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Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	<p>For micro-organisms, information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.</p> <p>Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any</p>	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.ResultsDetails

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	<p>other information on results incl. tables'. Upload predefined or other appropriate table(s) if available, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>As appropriate also attach a figure with growth curves in field 'Attached background material'.</p> <p>Note: Specific tables may be required.</p>		
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	<p>Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	<p>Any other information on results incl. tables Block</p>	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	<p>Overall remarks, attachments – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.OverallRemarksAttachments
Applicant's summary and conclusion	<p>Applicants summary and conclusion – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ApplicantSummaryAndConclusion

8.2.5 Long-term and chronic toxicity to aquatic invertebrates

8.2.5.1 Reproductive and development toxicity to aquatic invertebrate species – Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g.:

- Group: Specify Invertebrate species;
- Time scale;
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects).

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ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa
Long-term toxicity to aquatic invertebrates			ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates
Study name / type	Select the study/ies from which the endpoint was derived	Endpoint reference field	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.Link
Animal group	Indicate the taxa for which the endpoint below was derived according to the classification given in the EU data requirements (e.g. earthworms, collembola, etc).	Multi-line text	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.AnimalGroup
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.TestOrganismsSpecies

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Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.Substance
Basis for effect	Select the type of effect for endpoint setting. Select 'not specified' if the effect concentration type is not known.	Multi select open list with remarks	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (e.g. EC10, LC10, NOEC).	Closed list	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range, use both numeric fields together with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.EffectConcentration
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not	Open list	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.KeyValueCsa.LongTermToxAquaInvertebrates.NominalMeasured

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	specified), acid equivalent or estimated. Select 'not specified' if not known.		
Long-term toxicity to aquatic invertebrates			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP.Discussion

Links to support material

Guidance Document on Tiered Risk Assessment for Plant Protection products for Aquatic Organisms in Edge-of-field Surface Waters in the Context of Regulation (EC) No 1107/2009 (SANTE-2015-00080, 15 January 2015) https://www.efsa.europa.eu/en/efsajournal/pub/3290_10.2903/j.efsa.2013.3290

8.2.5.1 Reproductive and development toxicity to aquatic invertebrate species – Endpoint summary

Purpose

Chemicals: A long-term or chronic toxicity study on aquatic invertebrates shall be provided for all active substances where exposure of surface water is likely and the substance is deemed to be stable in water, that is to say there is less than 90 % loss of the original substance over 24 hours via hydrolysis.

Microorganisms: Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.

ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv – v.6.4 (Final) [September 2020]

Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 211: <i>Daphnia magna</i> Reproduction Test US EPA OCSPP 850.1350 Mysid Chronic Toxicity Test OECD Test Guideline 242: Potamopyrgus antipodarum Reproduction Test OECD Test Guideline 243: Lymnaea stagnalis Reproduction Test OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment OECD Test Guideline 233: Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment OECD Test Guideline 225: Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment OPPTS 885.4650 Aquatic Invertebrate Range Testing, Tier III	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.SamplingAndAnalysis

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Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block Nominal and measured concentrations: For microorganisms :Average achieved dose in colony forming units (cfu) also must be reported.	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsIncTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.Result

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		remarks	sAndDiscussion.Effect Concentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.Result sAndDiscussion.Effect Concentrations.Effect Conc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Close list	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.Result sAndDiscussion.Effect Concentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.Result sAndDiscussion.Effect Concentrations.Conc BasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.Result sAndDiscussion.Effect Concentrations.Basis ForEffect
Remarks on result	This field can be used for: <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.Result sAndDiscussion.Effect Concentrations.RemarksOnResults

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	should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.		
Effect concentrations			
Details on results	<p>For microorganisms: Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.</p> <p>Briefly summarize relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.</p> <p>Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Text template	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.ResultsDetails
Results with reference substance (positive control)	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.OverallRemarksAttachments

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Attached background material			
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ApplicantSummaryAndConclusion

8.2.5.2 Sedimentdwelling organisms – Endpoint summary

<p>Purpose: Summarise the most relevant study results from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, for instance:</p> <ul style="list-style-type: none"> • Test guideline used; • Test species tested; • Route of exposure; • Exposure duration; <p>Toxic effects expressed as LCx and ECx and/or NOEC/LOEC.</p>
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ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP v1.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.KeyValueCsa
Freshwater sediment toxicity			ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.KeyValueCsa.FreshwaterSedimentTox
Study name / type		Endpoint reference field	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.KeyValueCsa.FreshwaterSedimentTox.Link
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter	Multi select open list with remarks	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.KeyValueCsa.FreshwaterSedimentTox.TestOrganisms

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	name of organism (species).		
Parent / metabolite		Closed list	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.KeyValueCsa.FreshwaterSedimentTox.ParentMetabolite
Substance		Entity reference field	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.KeyValueCsa.FreshwaterSedimentTox.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.KeyValueCsa.FreshwaterSedimentTox.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed. If it is a corrected value, please indicate why.	Closed list	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.KeyValueCsa.FreshwaterSedimentTox.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.KeyValueCsa.FreshwaterSedimentTox.EffectConcentration
Freshwater sediment toxicity			

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Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP.Discussion

Links to support material:

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. <https://doi.org/10.2903/j.efsa.2013.3290>

8.2.5.2 Sedimentdwelling organisms – Endpoint study record

Purpose:

In case there are indications of an accumulation of the purified active substance in aquatic sediment as a result of environmental fate studies or predictions, the impact on a sediment-dwelling organism shall be assessed by the determination of the chronic toxicity to *Chironomus riparius* or *Lumbriculus* spp. of the purified active substance. An appropriate alternative test species may be used where a recognised guideline is available.

The active substance shall be applied to either the water or the sediment phase of a water/sediment system and the test shall take account of the major route of exposure.

The EC10, EC20 and a NOEC of active substance in the overlying water and the sediment shall be reported in terms of mg substance/kg dry sediment and mg substance/L water.

ENDPOINT_STUDY_RECORD.SedimentToxicity v8.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SedimentToxicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SedimentToxicity.DataSource
Materials and methods	Material and methods – common block Applicable Test guidelines:	Header 1	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods

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	<p>OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment</p> <p>OECD Test Guideline 233: Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment</p> <p>OECD Test Guideline 225: Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment</p>		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestMaterials
Sampling and analysis		Header 2	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.SamplingAndAnalysis
Analytical monitoring	<p>Indicate whether test substance was monitored in the test solutions or suspensions.</p> <p>For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.SamplingAndAnalysis.AnalyticalMonitoring
Details on sampling	<p>If the concentration of test material was monitored, enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnSampling
Details on analytical methods	<p>If the concentration of test material was monitored, enter any details on the analytical methods used.</p>	Text template	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.S

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	Use freetext template and delete/add elements as appropriate. Copy any subheading(s) for the different matrices as appropriate.		amplingAndAnalysis.DetailsOnAnalyticalMethods
Test substrate		Header 2	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestSubstrate
Vehicle	Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility. If yes, specify in field 'Details on sediment and application'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestSubstrate.Vehicle
Details on sediment and application	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance thereof.	Text template	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestSubstrate.DetailsOnSedimentAndApplication
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestOrganisms
Test organisms (species)	Select the name of the species. If not available, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Details on test organisms	Enter any details that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms

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Study design		Header 2	ENDPOINT_STUDY_RE CORD.SedimentToxicity .MaterialsAndMethods.S tudyDesign
Study type	Indicate the study type, i.e. laboratory study, extended laboratory study (e.g. with a more natural substrate), semi-field study (mimicking a near-natural environment with ambient climatic conditions) or field study (using natural populations).	Open list with remarks	ENDPOINT_STUDY_RE CORD.SedimentToxicity .MaterialsAndMethods.S tudyDesign.StudyType
Test type	Select the appropriate test type.	Open list	ENDPOINT_STUDY_RE CORD.SedimentToxicity .MaterialsAndMethods.S tudyDesign.TestType
Water media type	Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine water.	Open list with remarks	ENDPOINT_STUDY_RE CORD.SedimentToxicity .MaterialsAndMethods.S tudyDesign.WaterMedia Type
Type of sediment	Indicate whether natural or formulated sediment was used as substrate.	Closed list with remarks	ENDPOINT_STUDY_RE CORD.SedimentToxicity .MaterialsAndMethods.S tudyDesign.TypeOfSedi ment
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RE CORD.SedimentToxicity .MaterialsAndMethods.S tudyDesign.LimitTest
Exposure duration	Indicate the exposure duration and, if applicable, the related exposure phase. Copy this block of fields for different phases as appropriate.		ENDPOINT_STUDY_RE CORD.SedimentToxicity .MaterialsAndMethods.S tudyDesign.ExposureDu ration
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RE CORD.SedimentToxicity .MaterialsAndMethods.S tudyDesign.ExposureDu ration.TotalExposureDu ration

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Exposure phase	Select the related exposure phase, i.e. total exposure duration, larvae from first generation (P), reproduction phase, larvae from second generation (F1) or other: (specify). As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.StudyDesign.ExposureDuration.ExposurePhase
Remarks	Enter any remarks related to the total exposure duration.	Text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.StudyDesign.ExposureDuration.Remarks
Exposure duration			
Post exposure observation period	Indicate the post-observation period (with unit) if appropriate, e.g. in the case of a reproduction test.	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.StudyDesign.PostExposureObservationPeriod
Test conditions		Header 2	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions
Hardness	Indicate water hardness as mg/L calcium carbonate equivalent values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.Hardness
Test temperature	Indicate test temperature values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. As appropriate state	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.TestTemperature

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	<p>the location (e.g. water bath, test chambers) and type of measurement (e.g. continuous monitoring). Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.</p>		
pH	<p>Indicate pH values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Indicate how mean pH is to be obtained. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.Ph
Dissolved oxygen	<p>Indicate dissolved oxygen values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.DissolvedOxygen
Salinity	<p>For marine studies, indicate salinity (if relevant) values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.Salinity

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Ammonia	Indicate the ammonia concentration measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.Ammonia
Conductivity	Indicate conductivity values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.Conductivity
Nominal and measured concentrations	List nominal and, if available, measured test concentrations used in the study. As appropriate tabulate nominal vs. measured concentrations in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required. Consult the programme-specific guidance thereof.	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.NominalAndMeasuredConcentrations

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Details on test conditions	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance thereof.	Text template	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.DetailsOnTestConditions
Reference substance (positive control)	Indicate if a positive control was tested, i.e. a reference substance with known toxicity. If yes, include the identity of the substance(s) and the concentrations in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.TestConditions.ReferenceSubstancePositiveControl
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SedimentToxicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.

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			EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for	Open list with remarks	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn

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	<p>specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.</p>		
Basis for effect	<p>Select effect parameter such as development, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field, e.g. 'mean development rate, male and female midges pooled'.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults

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	<p>explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>		
Effect concentrations			
Details on results	<p>Briefly summarise relevant observations and any dose response relationship. Select freetext template for the respective type of study and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). As appropriate also attach a figure with growth curves in field 'Attached background material'. Note: Specific tables may be required.</p>	Text template	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.ResultsDetails
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.ResultsRefSubstance

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Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SedimentToxicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.SedimentToxicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SedimentToxicity.ApplicantSummaryAndConclusion

Links to support material:

OECD Guidelines for the testing of chemicals, Section 2 (Effects on biotic systems): https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-2-effects-on-biotic-systems_20745761

8.2.6 Effects on algae growth - Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details e.g

Chemicals: Growth rate, Biomass, Yield EC50/NOEC.

Microorganisms: Effects on algal growth, growth rate and capacity to recover

ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP – v.1.3 (Final) [October 2020]

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Name	Instructions	Data type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa
Toxicity to algae			ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae
Study name / type	Select the study from which the endpoint was derived.	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.Link
Test organisms (species)	Select the species from the picklist. If not available, select 'other:' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.Substance
Basis for effect	Select the type of effect for the endpoint setting.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (e.g. EbC10, ErC20, NOEC).	Closed list	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.DoseDescriptor

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Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.EffectConcentration
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Open list	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValueCsa.ToxAlgae.NominalMeasured
Toxicity to algae			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.Discussion

Links to support material:

Guidance Document on Tiered Risk Assessment for Plant Protection products for Aquatic Organisms in Edge-of-field Surface Waters in the Context of Regulation (EC) No 1107/2009 (SANTE-2015-00080, 15 January 2015)

https://www.efsa.europa.eu/en/efsajournal/pub/3290_10.2903/j.efsa.2013.3290

8.2.6 Effects on algae growth - Endpoint study record

Purpose

Information on effects on algal growth, growth rate and capacity to recover must be reported.

A test shall be provided establishing EC10, EC20, EC50 for green algae and corresponding NOEC values for algal growth rate and yield, based on measurements of biomass or surrogate measurement variables.

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ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae – v.7.6 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 201: Algae growth inhibition test is relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block Nominal and measured concentrations: the average achieved dose and relevant units must be reported.	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.TestConditions

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Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsIncludedTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal /	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToA

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measured	mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.		quaticAlgae.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	Information on effects on algal growth, growth rate and capacity to recover must be reported. Briefly summarise relevant observations and any dose response relationship. Use freetext template and	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.ResultsDetails

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	<p>delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>As appropriate also attach a figure with growth curves in field 'Attached background material'.</p> <p>Note: Specific tables may be required.</p>		
Results with reference substance (positive control)	<p>Results with reference substance (positive control) - If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide EC50 data and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	<p>Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.</p> <p>In addition, report the growth curves and the graphical presentation of the concentration-effect relationship.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	<p>Any other information on results incl. tables Block</p>	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	<p>Overall remarks, attachments – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.OverallRemarksAttachments
Applicant's summary and conclusion	<p>Applicants summary and conclusion – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ApplicantSummaryAndConclusion

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8.2.7 Effects on aquatic macrophytes - Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g., species, growth rate, Biomass, Yield ECx/NOEC.

ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP – v.1.3 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.AdministrativeDataSummary
Description of key information	Enter a short description of the most relevant endpoint data. The short description could include for example: -the test guideline used, -the test organism, -the exposure duration, -the contextual information of the origin of the value, -qualitative characterisation of some properties. The results (i.e. biological findings) should be presented in tabular format.	Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyInformation
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa
Toxicity to aquatic plants			ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants
Study name / type	Select the study from which the endpoint was derived	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.Link
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species)	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.TestOrganismsSpecies

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Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.Substance
Basis for effect	Select the type of effect for the endpoint setting.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (e.g NOEbC, EYC20).	Closed list	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. In mg or µg a.s./L	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.EffectConcentration
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Open list	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.NominalMeasured
Toxicity to aquatic plants			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies).	Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityPlants_EU_

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			PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.Discussion

Links to support material

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

8.2.7 Effects on aquatic macrophytes - Endpoint study record

Purpose

Information on effects on plants other than algae must be reported.

A test shall be provided establishing EC10, EC20, EC50 and corresponding NOEC values for Lemna species growth rate and yield, based on measurements of number of fronds and at least one additional measurement variable (dry weight, fresh weight or frond area).

For other species of aquatic macrophytes, a test shall provide sufficient information to evaluate impact on aquatic plants and provide EC10, EC20, EC50 and corresponding NOEC values based on measurement of appropriate biomass parameters.

ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant – v.7.7 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.Data Source
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.Data Source.Reference
Materials and methods	Material and methods – common block Applicable test guideline:	Header 1	ENDPOINT_STUDY_RECORD.ToxicityT

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	<p>OECD Test Guideline 221: <i>Lemna sp.</i> Growth Inhibition Test</p> <p>ASTM E1913-04: Standard Guide for Conducting Static, Axenic, 14-Day Phytotoxicity Tests in Test Tubes with the Submersed Aquatic Macrophyte, <i>Myriophyllum sibiricum Komarov</i></p> <p>OECD Test Guideline 238: Sediment-Free <i>Myriophyllum Spicatum</i> Toxicity Test</p> <p>OECD Test Guideline 239: Water-Sediment <i>Myriophyllum Spicatum</i> Toxicity Test</p> <p>OPPTS 885.4300 Nontarget Plant Studies, Tier I</p>		oAquaticPlant.Mate rialsAndMethods
Test material	Test material – common block	Head er 2	ENDPOINT_STUDY _RECORD.ToxicityT oAquaticPlant.Mate rialsAndMethods.Te stMaterials
Test material information	Test material	Entit y refer ence field	ENDPOINT_STUDY _RECORD.ToxicityT oAquaticPlant.Mate rialsAndMethods.Te stMaterials.TestMat erialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Head er 2	ENDPOINT_STUDY _RECORD.ToxicityT oAquaticPlant.Mate rialsAndMethods.Sa mplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Head er 2	ENDPOINT_STUDY _RECORD.ToxicityT oAquaticPlant.Mate rialsAndMethods.St udyDesign
Test conditions	Test conditions block	Head er 2	ENDPOINT_STUDY _RECORD.ToxicityT oAquaticPlant.Mate rialsAndMethods.Te stConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Head er 2	ENDPOINT_STUDY _RECORD.ToxicityT oAquaticPlant.Mate rialsAndMethods.A nyOtherInformatio nOnMaterialsAndM ethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Head er 1	ENDPOINT_STUDY _RECORD.ToxicityT

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			oAquaticPlant.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Actual achieved dose in relevant units must be reported. Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of	Open list with	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.Ef

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	<p>these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification.</p> <p>Select 'not specified' if the effect concentration type is not known.</p>	remarks	fectConcentrations. ConcBasedOn
Basis for effect	Select effect parameters such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.BasisForEffectMulti
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	<p>Any abnormal adverse or beneficial effects in treatment and/or control groups, including dates and times the effects were observed, should be reported.</p> <p>Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.</p> <p>Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.ResultsDetails

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	predefined or other appropriate table(s) if available, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').		
Results with reference substance (positive control)	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ApplicantSummaryAndConclusion

8.3 Effect on arthropods including bees - Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g.:</p> <ul style="list-style-type: none"> - Group: Specify species; - Route/time-scale - Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects); - Test type (laboratory/others); - Dose (kg /ha).

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ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP – v.1.2 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa
Short-term toxicity to terrestrial/soil arthropods			ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods
Study name / type	Select the study from which the endpoint was derived	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.Link
Animal group	Select the taxa for which the endpoint below was derived according to the classification given in data requirements (e.g. bees, soil dwelling arthropods and other non-target terrestrial arthropods).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.AnimalGroup
Test organisms (species)	Select species from picklist. If not available, select 'other' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.ParentMetabolite

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Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.Substance
Basis for effect	Select the basis for effect from which the endpoint was derived. If not available, select 'other:' and enter name of the basis for effect.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.BasisForEffect
Dose descriptor	Select the dose descriptor(s) associated to the endpoint assessed. If it is a corrected value, please indicate why.	Open list	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. Select the relevant units e.g µg/bee or CFU/bee.	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.ShortTermToxTerrestrialArthropods.EffectConcentration
Short-term toxicity to terrestrial/soil arthropods			
Long-term toxicity to terrestrial/soil arthropods			ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods
Study name / type	Select the study from which the endpoint was derived	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.Link

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Animal group	Select the taxa for which the endpoint below was derived according to the classification given in data requirements (e.g. bees, soil dwelling arthropods and other non-target terrestrial arthropods).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.AnimalGroup
Test organisms (species)	Select the species from the picklist. If not available, select 'other:' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.Substance
Basis for effect	Select the type of effect for endpoint(s) setting from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.BasisForEffect
Dose descriptor	Select the dose descriptor(s) associated to the endpoint assessed. If it is a corrected value, please indicate why.	Open list	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.EffectConcentration

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	<p>field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable Select the relevant units e.g µg/bee/day, µg/larva/developmental period or g/ha</p> <p>Also, for micro-organisms, average achieved dose in colony forming units (cfu) must be reported.</p>		
Long-term toxicity to terrestrial/soil arthropods			
Higher tier testing for safety assessment	<p>Provide information about higher tier testing (e.g. modelling or field studies for the different taxa). Is there potential for accumulative toxicity</p>	Header 1	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.HigherTierTesting.field1350

Links to support material:

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) [10.2903/j.efsa.2013.3295](https://www.efsa.europa.eu/en/technical-panels/10.2903/j.efsa.2013.3295)

Candolfi et al (2001). Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products With Non-Target Arthropods: From the Escort 2 Workshop (European Standard Characteristics of Non-Target Arthropod Regulatory Testing). SETAC press, pp 46. ISBN 1-880611-52-x.

Alix et al, 2012. ESCORT 3 – linking non-target arthropod testing and risk assessment with protection goals. CRC SETAC Press, 1–151.

Schaeffer et al (2017): Semi-Field Methods for the Environmental Risk Assessment of Pesticides in Soil, CRC Press

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8.3 Effect on arthropods including bees - Endpoint study record

Purpose

Bees

Information on toxicity, infectiveness and pathogenicity to bees must be reported. Effects on bees shall be assessed and the risk evaluated, including the risk deriving from residues of the active substance or its metabolites in nectar, pollen and water, including guttation.

- A test for acute oral toxicity shall be provided establishing the acute LD₅₀ values together with the NOEC. Sub-lethal effects, if observed, shall be reported.
- A test for acute contact toxicity shall be provided establishing the acute LD₅₀ values together with the NOEC. Sub-lethal effects, if observed, shall be reported.
- A test for chronic toxicity to bees shall be provided establishing the chronic oral EC₁₀, EC₂₀, EC₅₀ together with the NOEC. Where the chronic oral EC₁₀, EC₂₀, EC₅₀ cannot be estimated, an explanation shall be provided. Sub-lethal effects, if observed, shall be reported.
- A bee brood study shall be conducted to determine effects on honeybee development and brood activity. The bee brood study shall provide sufficient information to evaluate possible risks from the active substance on honeybee larvae.
- The test shall provide the EC₁₀, EC₂₀ and EC₅₀ for adult bees, where possible, and larvae together with the NOEC. Where EC₁₀, EC₂₀, EC₅₀ cannot be estimated, an explanation shall be provided. Sub-lethal effects, if observed, shall be reported.
- Tests investigating sub-lethal effects, such as behavioural and reproductive effects, on bees and, where applicable, on colonies may be required.

Non-target arthropods other than bees

Information on toxicity, infectiveness and pathogenicity to arthropods other than bees must be reported. The selection of the test species should be related to the potential use of the plant protection products (e.g. foliar or soil application). Special attention should be given to organisms used for biological control and organisms playing an important role in integrated pest management. Effects on non-target terrestrial arthropods shall be investigated for all active substances except where plant protection products containing the active substance are for exclusive use in situations where non-target arthropods are not exposed.

A test shall provide sufficient information to evaluate the toxicity in terms of LR50 and NOEC of the active substance to *Aphidius rhopalosiphi*.

A test shall provide sufficient information to evaluate the toxicity in terms of LR50 and NOEC of the active substance to *Typhlodromus pyri*.

ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods – v.7.3 (Final) [September 2020]

Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: EPPO Standard PP1/170 (4): Test methods for evaluating the side-effects of plant protection products on honeybees OECD Test Guideline 213: Honeybees, Acute Oral Toxicity Test OECD Test Guideline 247: Bumblebee, Acute Oral Toxicity Test OECD Test Guideline 214: Honeybees, Acute Contact Toxicity Test OECD Test Guideline 246: Bumblebee, Acute Contact Toxicity Test OECD Test Guideline No. 237 - Honey Bee (Apis Mellifera) Larval Toxicity Test, Single Exposure OECD Series on Testing & Assessment No. 239; Guidance Document on Honey Bee Larval Toxicity Test following Repeated Exposure M.P. Candolfi, S. Blümel, R. Forster et al. (2000): Guidelines to evaluate side-effects of	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods

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	plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative. ISBN: 92-9067-129-7. OPPTS 885.4380 Honey Bee Testing, Tier I OPPTS 885.4340 Nontarget Insect Testing, Tier I		
Application method	Select as method of application as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.ApplicationMethod
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestOrganisms
Test organisms (species)	Select species from picklist. If not available, select 'other' and enter name of organism (species).	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Animal group	Indicate the animal group, e.g.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrest

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	'Hymenoptera (honeybees)' for honeybees or 'Collembola (soil-dwelling springtail)' for a test with <i>Folsomia candida</i> . Helpful for searching purposes.		rialArthropods.MaterialsAndMethods.TestOrganisms.AnimalGroup
Details on test organisms	Enter any details that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions BLOCK (OHT: Terrestrial tox.) Nominal and measured concentrations : For microorganisms average achieved dose in colony forming units (cfu) must be reported.	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion
Toxic reference	Specify the toxic reference considered in the study.	Text area	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsA

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			ndDiscussion.ToxicReference
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.NominalMeasured

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	weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.		
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as behaviour, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectCon

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	<p>numeric value(s) were derived;</p> <ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>		<p>centrations.RemarksOn Results</p>
Effect concentrations			
Details on results	<p>For microorganisms indicate that information on toxicity, infectiveness and pathogenicity to bees and arthropods other than bees must be</p>	Text template	<p>ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.ResultsDetails</p>

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	<p>reported. The text from the US EPA guideline could also be included afterwards. The guideline should be cited (885.4340 - Nontarget Insect Testing, Tier I (February 1996)).</p> <p>Briefly summarise relevant observations and any dose response relationship. Depending on the type of study, select appropriate freetext template (i.e. soil or above-ground arthropods or honeybees) and delete/add elements as appropriate.</p> <p>Include the following information, for bees (pollinators): Lower tier - LD50 and NOED values and potentially differentiate between the types of test (i.e. acute oral, acute contact, chronic and life stage (adult / larvae), the species)) Higher tier – could have fields to indicate the major effects e.g. mortality, behaviour, brood development and colony strength but also could just have the standard text fields (Key Information, Additional information). The residue measurements/pollen</p>		
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	<p>characterisation (to guarantee the proper exposure).</p> <p>Information on Non-target arthropods: Lower tier: EC50, LR50, ER50 values (separate section or separate summary), type of exposure, species (For this type of studies optional reporting of NOEC).</p> <p>Higher tier: EC50, LR50, ER50, NOAER, NOER values (separate section or separate summary), type of exposure, species. (For this type of studies optional reporting of NOEC).</p> <p>Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Ability to record multiple endpoint values (we can have different species, populations, communities etc.)</p>		
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	<p>For microorganisms - The most appropriate end-point for protozoan diseases for determining pathogenic effects is the presence of the vegetative stages (shizonts or meronts) in the tissues of nontarget insects; Mortality time, expressed as LT50 (time course of population mortality), is considered the most reliable parameter for bioassaying fungi of insects in the laboratory</p> <p>Relevant information to record for higher tier. Study site/location, irrigation or other application techniques, sampling method, crop rotation in field study, as well as the field history concerning agricultural management (including PPPs) should be reported.</p>		
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.ResultsReferenceSubstance
Reported statistics and error estimates	<p>Indicate the parameters analysed, the statistical</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToTerrest

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	method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.		rialArthropods.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ApplicantSummaryAndConclusion

8.4.1 Effects on non-target soil meso- and macrofauna – Endpoint summary

<p>Purpose Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details.</p> <ul style="list-style-type: none"> - Group: Specify species; - Route/time-scale - Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects); - Test type (laboratory/others); - Dose (kg /ha).

ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP – v.1.1.2 (Final) [October 2020]			
Name	Instructions	Data type	Field path

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Administrative data	Administrative data summary – common block Description of key information example: -“Chronic toxicity to annelids: EC ₅₀ reproduction >=2000 a.s. mg/kg soil dw for <i>Eisenia fetida</i> (OECD 222; Chronic)”	Header 1	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment	Section specific for reporting of tier 1 studies.	Header 1	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa
Short-term toxicity to soil macroorganisms except arthropods	Short term (acute) studies to soil macroorganisms are no longer required.		ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms
Study name / type	Select the study from which the endpoint was derived.	Endpoint reference field	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.Link
Animal group	Indicate the taxa for which the endpoint below was derived according to the classification given in the data requirements (e.g. earthworms).	Multi-line text	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.AnimalGroup
Test organisms (species)	Select the species from the picklist. If not available, select 'other:' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.Substance

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Details on preparation and application of test substance	Provide details on the form the substance was applied in the test.	Rich text area	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.PreparationApplicationTestSubstance
Basis for effect	Select the type of effect for endpoint(s) setting from the picklist. If not available, select 'other' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (EC50 or LC50).	Closed list	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable. In mg a.s./kg d.w.soil (mg a.s/ha). For micro-organisms, average achieved dose in colony forming units (cfu) also must be reported.	Range with open list (Decimal)	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganisms.EffectConcentration
Short-term toxicity to soil macroorganisms except arthropods			
Long-term toxicity to soil macroorganisms except arthropods			ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms
Study name / type	Select the study from which the endpoint was derived.	Endpoint reference	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.L

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		nce field	ongTermToxicitySoilOrganisms.Link
Animal group	Indicate the taxa for which the endpoint below was derived according to the classification given in the requirements (e.g. earthworms).	Multi-line text	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.AnimalGroup
Test organisms (species)	Select species from the picklist. If not available, select 'other:' and enter the species name of the test organism.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.Substance
Details on preparation and application of test substance	Provide details on how the substance was applied in the test (e.g. soil incorporation, mixed into the soil).	Rich text area	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.PreparationApplicationTestSubstance
Basis for effect	Select the type of effect for endpoint(s) setting from picklist. If not available, select 'other' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed (e.g. "EC10, EC20, NOEC.	Open list	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.DoseDescriptor
Effect concentration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields	Half-bound ed with	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.L

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	together with the appropriate qualifier(s), if applicable. In mg a.s./kg d.w.soil (mg a.s/ha). For micro-organisms average achieved dose in colony forming units (cfu) must be reported.	open list (Decimal)	ongTermToxicitySoilOrganisms.EffectConcentration
Long-term toxicity to soil macroorganisms except arthropods			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.Discussion

Links to support material:

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

8.4.1 Effects on non-target soil meso- and macrofauna - Endpoint study record

Purpose

A test shall provide information on the effects on growth, reproduction and behaviour of the earthworm.
 Testing shall determine a dose-response relationship and the EC₁₀, EC₂₀ and NOEC shall enable the risk assessment to be conducted in accordance with the appropriate risk quotient analysis, taking into account likely exposure, the organic carbon content (foc) of the test medium and the lipophilic properties (Kow) of the test substance.
 Information on toxicity, infectiveness and pathogenicity to earthworms must be reported.

ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods – v.6.3 (Final) [September 2020]

Name	Instructions	Data type	Field path
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Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 222: Earthworm Reproduction Test (<i>Eisenia fetida</i> / <i>Eisenia andrei</i>) ISO 11268-3:2014: Soil quality - Effects of pollutants on earthworms - Part 3: Guidance on the determination of effects in field situations ISO 23611-1:2018: Soil quality - Sampling of soil invertebrates - Part 1: Hand-sorting and extraction of earthworms	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestOrganisms

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Test organisms (species)	Select species from the picklist. If not available, select 'other' and enter the species name of the test organism.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies
Animal group	Indicate the animal group, e.g. 'annelids' for a test with a worm species. Helpful for searching purposes.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestOrganisms.AnimalGroup
Details on test organisms	Enter any details that could be relevant for evaluating this study summary. Use free-text template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions BLOCK (OHT: Terrestrial tox.) Nominal and measured concentration: Average achieved dose in colony forming units (cfu) must be reported.	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion

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Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn

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	<p>it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.</p>		
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'; <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	<p>Information on toxicity, pathogenicity and infectiveness to earthworms should be reported.</p> <p>Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.ResultsDetails
Results with reference	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDisc

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substance (positive control)	Use freetext template and delete/add elements as appropriate.		ussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ApplicantSummaryAndConclusion

8.4.3 Bioaccumulation: terrestrial – Endpoint summary

Purpose: Provide information on the bioaccumulation potential of the active substance and/or its metabolites in terrestrial organisms

ENDPOINT_SUMMARY.BioaccumulationTerrestrial v5.0 Final			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BioaccumulationTerrestrial.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.BioaccumulationTerrestrial.KeyValueForChemicalSafetyAssessment

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BCF (terrestrial species)		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BioaccumulationTerrestrial.KeyValueForChemicalSafetyAssessment.BcfTerrestrialSpecies
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.BioaccumulationTerrestrial.Discussion

Links to support material

Appendix S of EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp.

<https://doi.org/10.2903/j.efsa.2009.1438>

8.4.3 Bioaccumulation: terrestrial – Endpoint study record

Purpose:

The bioaccumulation of the active substance and its pertinent metabolites in terrestrial vertebrates should be determined.

Bioaccumulation often correlates with lipophilicity, thus, for organic chemicals, a log Kow > 3 indicates a potential for bioaccumulation.

The bioaccumulation is estimated from the food-organism bioaccumulation factor:

BAF = C_{organism} / C_{food}; where C_{organism} and C_{food} represent the steady-state concentrations of the chemical in the organism and food, respectively.

The BAF can be directly obtained from experimental assays or estimated from a combination of default values and the available data on the toxicokinetics of the pesticide in mammals.

ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial v7.3 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.Data Source

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Materials and methods	Material and methods – common block Applicable test guideline: OECD TestGuideline 226: Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in Soil.	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.TestMaterials.Radiolabelling
Sampling and analysis		Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.SamplingAndAnalysis
Details on sampling	Enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnSampling
Details on analytical methods	Enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Specify treatment of animal and soil samples, including details of preparation,	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnAnalyticalMethods

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	storage, extraction and analytical procedures (and precision) for the test substance and lipid content (if measured). Copy any subheading(s) for the different matrices as appropriate.		
Test substrate		Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.TestSubstrate
Vehicle	Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility. If yes, specify in field 'Details on preparation and application of test substrate'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.TestSubstrate.Vehicle
Details on preparation and application of test substrate	Enter any details that could be relevant for evaluating this study summary. Use freetext template as appropriate.	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.TestSubstrate.DetailsOnPreparationAndApplicationOfTestSubstrate
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.TestOrganisms
Test organisms (species)	Select species from picklist. If not available, select 'other' and enter name of organism (species).	Open list	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies

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Details on test organisms	Enter any details that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.TestOrganisms.DetailsOfTestOrganisms
Study design		Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.StudyDesign
Total exposure / uptake duration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.StudyDesign.TotalExposureUptakeDuration
Total depuration duration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.MaterialsAndMethods.StudyDesign.TotalDepurationDuration
Test conditions		Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.Mate

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			rialsAndMethods.Tes tConditions
Test temperature	Indicate test temperature values measured during test. Include range, mean, standard deviation and unit. As appropriate state the location and type of measurement (e.g. continuous monitoring). Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	Multi-line text	ENDPOINT_STUDY_ RECORD.Bioaccumul ationTerrestrial.Mate rialsAndMethods.Tes tConditions.TestTem perature
pH	Indicate pH values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	Multi-line text	ENDPOINT_STUDY_ RECORD.Bioaccumul ationTerrestrial.Mate rialsAndMethods.Tes tConditions.Ph
TOC	Indicate TOC (total organic carbon) values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	Multi-line text	ENDPOINT_STUDY_ RECORD.Bioaccumul ationTerrestrial.Mate rialsAndMethods.Tes tConditions.TOC
Moisture	Indicate the soil humidity in %	Multi-line text	ENDPOINT_STUDY_ RECORD.Bioaccumul

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	moisture content or g water/100g soil dry weight measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.		ationTerrestrial.Mate rialsAndMethods.Tes tConditions.Moisture
Details on test conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_ RECORD.Bioaccumul ationTerrestrial.Mate rialsAndMethods.Tes tConditions.DetailsO nTestConditions
Nominal and measured concentrations	List nominal and, if available, measured test concentrations in soil and the measured concentrations in tissues (with unit, i.e. mg/kg soil d.w., g/kg soil d.w., g/ha d.w., kg/ha d.w. or other). As appropriate tabulate the data and refer to Table No. (use predefined table if any). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_ RECORD.Bioaccumul ationTerrestrial.Mate rialsAndMethods.Tes tConditions.Nominal AndMeasuredConcen trations
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_ RECORD.Bioaccumul ationTerrestrial.Mate rialsAndMethods.Any OtherInformationOn

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			MaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion
Lipid content	Indicate the lipid content of test organisms with unit. If appropriate specify the time point at which the measurement was made, e.g. start or end of experiment. Copy this block of fields for specifying the lipid content ratio in % if required.		ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.LipidContent
Lipid content	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.LipidContent.LipidContent
Time point	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.LipidContent.TimePoint
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.LipidContent.RemarksOnResults

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	<p>reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or</p> <p>- entering any additional information on the effect level by selecting 'other:'.</p>		
Lipid content			
Bioconcentration factor	<p>This repeatable block of fields allows to report the steady-state BAF (bioaccumulation factor), BSAF (biota-to-soil accumulation factor) and/or BCF (bioconcentration factor, where pore water is the basis). Copy this block of fields if more than one value should be entered, e.g. kinetic bioaccumulation factors expressed in relation to the whole body, the total lipid content or specific tissues of the test organisms.</p>		<p>ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.BioaccumulationFactor</p>
Key result	<p>Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD</p>	<p>Check box</p>	<p>ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.BioaccumulationFactor.KeyResult</p>

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	Programme, Pesticides NAFTA or EU REACH) on how to use this field.		
Type	Indicate the reported bioaccumulation factor, i.e. either BAF, the steady-state BSAF (biota-to-soil accumulation factor) or BCF (bioconcentration factor, where pore water is the basis).	Closed list	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.BioaccumulationFactor.Type
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.BioaccumulationFactor.Value
Basis	From drop-down list, select the basis for the BAF, i.e. expressed in relation to the whole body, the total lipid content or specific tissues of the test organisms (w.w. = wet weight; d.w. = dry weight).	Open list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.BioaccumulationFactor.Basis
Time of plateau	If applicable, indicate time at which plateau was reached (for tissue concentration).	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.BioaccumulationFactor.TimeOfPlateau
Calculation basis	If the BAF was not calculated at steady	Open list with remarks	ENDPOINT_STUDY_RECORD.Bioaccumul

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	state, select 'kinetic:' and briefly specify using the supplementary remarks field (e.g. 'kinetic: steady state at 80% of equilibrium).		ationTerrestrial.ResultsAndDiscussion.BioaccumulationFactor.CalculationBasis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:', e.g. for indicating if bioconcentration / bioaccumulation is based on parent compound instead of radioactivity.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.BioaccumulationFactor.RemarksOnResults
Bioconcentration factor			
Depuration	Indicate if clearance of test substance or metabolites from test organisms was observed; give depuration time required for clearance of 50% (DT50), 90% (DT90) and or any		ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.Depuration

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	other percent of residues.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.Depuration.KeyResult
Elimination	Indicate whether elimination of test substance or metabolites occurred or not.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.Depuration.Elimination
Parameter	Indicate to which endpoint type the effect concentration refers, e.g. DT50.	Open list with remarks	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.Depuration.Endpoint
Depuration time (DT)	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.Depuration.Depuration Time
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.Depuration.RemarksOn Results

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	<p>explanation in the supplementary remarks field; or</p> <ul style="list-style-type: none"> - entering any additional information on the effect level by selecting 'other:'. 		
Depuration			
Kinetic parameters	<p>Give values (including 95 % confidence limits and standard deviations) for the uptake and depuration rate constants (all expressed in relation to whole body, total lipid content or specific tissues of the test organisms); give relevant details on computation/data analysis.</p>	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.KineticParameters
Metabolites	<p>If identified, table(s) with data on any metabolites of the test substance accumulated in test organisms (total), specific tissues thereof (e.g. lipid) should be included (at least those, accounting for > 10 % of residues).</p>	Text area	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.Metabolites
Details on results	<p>Report any other relevant results using freetext template as appropriate. Indicate any results related to the chemical properties of the test material. Compare the results for the test substance with that</p>	Text template	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.DetailsOnResults

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	for the reference substance.		
Reported statistics	Indicate the parameters analysed, the statistical method used and the statistical test performed.	Multi-line text	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.ReportedStatistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BioaccumulationTerrestrial.ApplicantSummaryAndConclusion

Links to support material

Appendix S of EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. <https://doi.org/10.2903/j.efsa.2009.1438>

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8.5 Effects on soil nitrogen transformation - Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details

Chemicals: long term effects on nitrogen transformation

Microorganisms: impact on relevant non-target micro-organisms and on their predators (e.g. protozoa for bacterial inoculants)

ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP – v.1.1 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment
Long-term toxicity to soil microorganisms			ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.Substance
Basis for effect	For chemicals: In line with the OECD test guideline the endpoint should be based on nitrogen transformation rate and not nitrogen levels (e.g. % effect at day xx at mg a.s./kg d.w.soil (mg a.s/ha)).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.BasisForEffect

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	For microorganisms: select other and add remark to report impact on soil microbial communities		
Dose descriptor	Select the dose descriptor associated with the endpoint assessed. If it is a corrected value, please indicate why.	Open list	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.DoseDescriptor
Effect value	Enter % effect at day xx at mg a.s./kg d.w.soil (mg a.s/ha)	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxSoilMicroorganisms.EffectValue
Long-term toxicity to soil microorganisms			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.Discussion

Links to support material:

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

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8.5 Effects on soil nitrogen transformation - Endpoint study record

Purpose

Impact on relevant non-target micro-organisms and on their predators (e.g. protozoa for bacterial inoculants) shall be reported. Expert judgement is required to decide whether additional studies are necessary. Such decision will take into consideration the available information in this Section and other Sections, in particular data on the specificity of the micro-organism, and the expected exposure. Useful information may also be available from the observations carried out in efficacy testing. Special attention shall be given to organisms used in integrated crop management (ICM).

A test shall provide sufficient data to evaluate the impact of active substances on soil microbial activity, in terms of nitrogen transformation.

ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms – v.6.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.Data Source
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.Data Source.Reference
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 216: Soil Microorganisms: Nitrogen Transformation Test OPPTS 850.5100 Soil Microbial Community Toxicity Test	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.Test Materials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.Test

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			Materials.TestMaterial Information
Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoil Microorganisms.MaterialsAndMethods.SamplingAndAnalysis
Test organisms		Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoil Microorganisms.MaterialsAndMethods.Test Organisms
Test organisms (inoculum)	Select 'soil' if soil samples were used as inoculum. Otherwise select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToSoil Microorganisms.MaterialsAndMethods.Test Organisms.TestOrganismsInoculum
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoil Microorganisms.MaterialsAndMethods.StudyDesign
Test conditions	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoil Microorganisms.MaterialsAndMethods.Test Conditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoil Microorganisms.MaterialsAndMethods.Any OtherInformationOn MaterialsAndMethods InclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoil Microorganisms.ResultsAndDiscussion
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToSoil Microorganisms.ResultsAndDiscussion.EffectConcentrations

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Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value and unit .	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration	Open list with	ENDPOINT_STUDY_RECORDER.ToxicityToSoilMicroorganisms.Result

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	relates to. As appropriate include further details in the supplementary remarks field.	remarks	tsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	<p>Report any other relevant results using freetext template as appropriate. As appropriate include table with raw data (use predefined table if any or adapt similar table from study report) and/or attach graph of the dose-response curve.</p> <p>For chemicals: The results of the range-finding test expressed as micrograms of CO₂ evolved per gram of dry soil per hour, and micrograms of each of NH₃ and NO₃ present per gram of dry soil, in treated and untreated samples. If the range-finding test indicated that the highest concentration of the test substance tested (but not less than 1,000 µg/g) had no effect on the test system, report the results by soil source and type and state that the test substance has a low potential for adversely affecting microbial functions in such soils. If the range-finding test indicated a greater than 50 percent reduction of the endpoints of the test at a concentration of the test substance that represents the analytical detection limit (if tested), report the results by soil source and type and state that the test substance is toxic to microbial life in such soils</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.ResultsDetails

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	at concentrations at or below the analytical detection limit used in this study. For microorganisms: impact on the soil microbial community should be evaluated		
Results with reference substance (positive control)	Results with reference substance (positive control) - Indicate whether the results with the reference substance(s) are valid.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ApplicantSummaryAndConclusion

8.6 Effects on terrestrial non-target higher plants - Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, e.g., effects on seedling emergence and/or vegetative vigour.

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ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP v.1.3			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.AdministrativeDataSummary
Key value for safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa
Toxicity to terrestrial plants			ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants
Study name / type		Endpoint reference field	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants.Link
Type of study	Select the study from which the endpoint was derived	Closed list	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants.TypeOfStudy
Test organisms (species)	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite	Closed list	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants.ParentMetabolite
Substance	Select the substance for which the endpoint was derived	Entity reference field	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants.Substance
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants.BasisForEffect

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	appropriate include further details in the supplementary remarks field.		
Dose descriptor	Select the dose descriptor associated to the endpoint assessed (e.g. ER10, ER50) .	Open list	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants.DoseDescriptor
Effect concentration	Report value in g/ha	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants.EffectConcentration
Toxicity to terrestrial plants			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. semi-field or field studies).	Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.Discussion

Links to support material

EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-

8.6 Effects on terrestrial non-target higher plants - Endpoint study record

Purpose:

A test shall provide the ER₅₀ values of the active substance to non-target plants
The information provided shall be sufficient to permit the evaluation of effects of the active substance on non-target plants.

ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants – v.6.4 (Final) [September 2020]

Name	Instructions	Data type	Field path
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Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test OECD Test Guideline 227: Terrestrial Plant Test: Vegetative Vigour Test OPPTS 885.4300 - Nontarget Plant Studies, Tier I	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling Test substrate BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.SamplingAndAnalysis
Test organisms	Indicate the species and corresponding plant group. As appropriate you can prepare a study summary for each species used in a given study or cover all species tested in one record. In the latter case, copy this field block and enter the information required for each species.	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestOrganisms
			ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.Test

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			Organisms.TestOrganisms
Species	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestOrganisms.TestOrganisms.Species
Plant group	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestOrganisms.TestOrganisms.PlantGroup
Details on test organisms	For robust study summaries or as requested by the regulatory programme, also include relevant details on the test organism in the respective subfield. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion

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Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.		ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.KeyResult
Species	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.Species
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed	Open list with	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.Result

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	fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	remarks	tsAndDiscussion.EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.BasisForEffect
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' <p>Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	<p>Observations and reporting 885.4300 - Nontarget Plant Studies, Tier I (February 1996): Any abnormal adverse or beneficial effects in treatment and/or control groups, including dates and times the effects were observed.</p> <p>Briefly summarise relevant observations and any dose response relationship. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.ResultsDetails

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	<p>predefined or other appropriate table(s) if any available, and tailor it/them to your needs or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>As appropriate also attach a figure with growth curves in field 'Attached background material'.</p>		
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.ResultsRefSubstance
Reported statistics and error estimates	<p>Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	<p>Any other information on results incl. tables Block</p>	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	<p>Overall remarks, attachments – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.OverallRemarksAttachments
Applicant's summary and conclusion	<p>Applicants summary and conclusion – common block</p>	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ApplicantSummaryAndConclusion

8.7 Effects on other terrestrial and aquatic organisms (flora and fauna)- Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details.

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ENDPOINT_SUMMARY.AdditionalEcotoxicologicalInformation v.3.0			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.AdditionalEcotoxicologicalInformation.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AdditionalEcotoxicologicalInformation.Discussion

8.7 Effects on other terrestrial and aquatic organisms (flora and fauna) - Endpoint study record

<p>Purpose</p> <p>The additional studies might include further acute studies on additional species or processes or higher tier studies such as chronic, sub-lethal or reproductive studies on selected non-target organisms.</p> <p>Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.</p>
--

ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation v.6.3			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.MaterialsAndMethods.AnyOtherInformationOnMat

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			erialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformation.ApplicantSummaryAndConclusion

8.8 Effects on biological methods for sewage treatment – Endpoint summary

Purpose:

Where the use of plant protection products containing the active substance can give rise to adverse effects on sewage treatment plants, effects of purified active substance on micro-organisms from activated sludge of waste-water treatment plants by measuring their respiration rate (carbon and/or ammonium oxidation) as oxygen consumption shall be determined and reported as ECx and/or NOEC values of the active substance.

ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment v1.2 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.KeyValueCsa
Effects on biological methods			ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.Key

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for sewage treatment			ValueCsa.EffectsBioMethodsSewageTreatment
Test organisms (species)	Select the test organism where the effect was observed (e.g. sludge activated).	Multi select open list with remarks	ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.KeyValueCsa.EffectsBioMethodsSewageTreatment.TestOrganismsSpecies
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.KeyValueCsa.EffectsBioMethodsSewageTreatment.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.KeyValueCsa.EffectsBioMethodsSewageTreatment.Substance
Basis for effect	Select the type of effect for the endpoint setting (e.g. percentage of inhibition).	Multi select open list with remarks	ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.KeyValueCsa.EffectsBioMethodsSewageTreatment.BasisForEffect
Dose descriptor	Select the dose descriptor associated with the endpoint assessed.	Closed list	ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.KeyValueCsa.EffectsBioMethodsSewageTreatment.DoseDescriptor
Effect concentration		Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.KeyValueCsa.EffectsBioMethodsSewageTreatment.EffectConc
Effects on biological methods for sewage treatment			
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment.Discussion

8.8 Effects on biological methods for sewage treatment - Endpoint study record

Purpose

Effects on biological methods for sewage treatment shall be reported where the use of plant protection products containing the active substance can give rise to adverse effects on sewage treatment plants.

Microorganisms Optional: There is no data requirement for toxicity to microorganisms however this document can be used if studies of this type are provided to support the application

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ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms v.8.4			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.DataSource
Reference	Literature reference		
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 209: Activated Sludge, Respiration Inhibition Test EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Sampling and analysis	Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.MaterialsAndMethods.SamplingAndAnalysis
Study design	Study design BLOCK (OHT: Aquatic tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.MaterialsAndMethods.StudyDesign
Test conditions	Test conditions block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

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Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms.ApplicantSummaryAndConclusion

8.9 Monitoring data – Endpoint summary

Purpose:

Available monitoring data concerning effects of the active substance/plant protection product to non-target organisms shall be reported.

ENDPOINT_SUMMARY.BiologicalEffectsMonitoring v.3.0 (Final) [July 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BiologicalEffectsMonitoring.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.BiologicalEffectsMonitoring.Discussion

8.9 Monitoring data – Endpoint study record

Purpose:

Summary information of the most relevant findings should be reported. Enter a short description of the most relevant endpoint data. The short description could include for example:

- used method
- organism monitored
- related test conditions
- final results

ENDPOINT_STUDY_RECORD.BiologicalEffectsMonitoring v.6.3 (Final) [September 2020]			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BiologicalEffectsMonitoring.AdministrativeData

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Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.MaterialsAn dMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.MaterialsAn dMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.MaterialsAn dMethods.AnyOtherInfo rminationOnMaterialsAnd MethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.ResultsAndD iscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.ResultsAndD iscussion.AnyOtherInfor mationOnResultsInclTa bles
Overall remarks, attachments		Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.OverallRema rksAttachments
Overall remarks	Overall remarks, attachments – common block	Rich text area	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.OverallRema rksAttachments.Remark sOnResults
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RE CORD.BiologicalEffects Monitoring.ApplicantSu mmaryAndConclusion

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9 Literature data and change log

9.1 Literature data

<p>Purpose: Description of the methodology used for the search for all relevant data from scientific peer reviewed open literature List of all relevant studies retrieved</p>
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FLEXIBLE_RECORD.LiteratureSearch – v.5.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Header 1	FLEXIBLE_RECORD.LiteratureSearch.AdministrativeData
		Confidentiality	FLEXIBLE_RECORD.LiteratureSearch.AdministrativeData.DataProtection
Link to relevant studies	<p>Link to all Literature Reference entities that were retrieved from the literature search and are considered relevant and reliable after the full text screening step.</p> <p>An appropriate Endpoint Study Record should be completed for each relevant study and the literature reference included in the data source section.</p>	Header 1	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies
Literature reference(s)		Literature reference list	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.LiteratureReference
Description of key information	Summary of all relevant data from the scientific peer reviewed open literature on the active substance, metabolites	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.KeyInformationDesc

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	and breakdown or reaction products and plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species		
Overall summary of the literature search	<p>Summary of the methodology used to retrieve relevant studies on side-effects on health, the environment and non-target species.</p> <p>Report the criteria used to classify the references as being clearly non-relevant (e.g. not related to pesticides).</p> <p>Report the criteria used to assess the reliability of the studies.</p>	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.SearchSummary
Search strategy	Indicate how the literature search was carried out.	Header 1	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy
Bibliographic databases used in the literature review and search results	A description each of the search strategies used in the literature review		FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed
Online search service	Select the database/source where the search was performed. Use other to indicate a database/source that is not included in the list. The remarks field should contain the justification for selecting the database/source. More	Open list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.SearchService

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	information on databases/sources Is provided in the supporting materials below		
Date of search	Provide the date when the search was performed using the database.	Date	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Date
Time window of the literature search	The period covered in the literature search e.g. 2010 to 2020	Text	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.TimeWindow
Search string(s) used	<p>The search strings used to retrieve the records e.g.</p> <ol style="list-style-type: none"> 1. ts=Chlorpyrifos 2. ts=(Brodan or Detmol or Dowco 179 or Dursban or eradex or Lorsban or Paqeant or Piridane) 3. ts=((scout or stipend or empire) and (pesticide* or insect*)) 4. #3 OR #2 OR #1 <p>More examples are provided in the supporting materials below</p>	Multi-line text	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Strings
Filters	Indicate if filters were applied in the search. If yes is selected the filters applied must be described	Closed list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Filters
Limits	Indicate if any limits were applied in the search, for example only studies in English. If yes is the limits applied must be described	Closed list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Limits

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Number of hits	The number of hits for the search in each database/source	Integer	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.NoHits
Number of hits after refinement	The number of hits after refinement, if applicable	Integer	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.NoHitsRefinement
Number of hits after duplicate removal	The number of hits after duplicate removal	Integer	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.NoHitsDuplicate
Bibliographic databases used in the literature review and search results			
Evaluation of the review		Header 1	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview
Records retrieved	The number of records retrieved when the results for the searches above where combined	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.RecordsRetrieved
Records after removal of duplicates	Total number of summary records retrieved after removing duplicates from all database searches	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoAfterDuplicates
Records after rapid assessment	Report the number of records retained after title/abstract screening	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoRapidAssessment
Records after detailed assessment	Report the number of records retained after full text screening	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoDetailedAssessment
Reliable studies	Report the number of records retained after the reliability assessment	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ReliableStudies
Evaluated studies	Number of studies included in the dossier, reported in an endpoint study record and used	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.EvaluatedStudies

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	as supporting information. These studies should be listed in the Literature reference(s) field and the number should be the same.		
Publications excluded from the risk assessment after detailed assessment of full-text documents	For each of the studies excluded on the basis of relevance or reliability link to the Literature Reference entity and describe the reason for exclusion		FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications
Literature reference	Link a reference to the excluded publication.	Literature reference list	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications.LitReference
Exclusion reason	Reason for not including publication in dossier (based on relevance and reliability criteria).	Multi-line text	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications.ExclusionReason
Publications excluded from the risk assessment after detailed assessment of full-text documents	For each of the studies excluded on the basis of relevance or reliability link to the Literature Reference entity and describe the reason for exclusion		
Additional information		Header 1	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation
Additional information	Any other information needed to interpret the results for the literature research	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.AdditionalInfo
Attached background material	Upload supporting files e.g bibliographic metadata		FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial
Attached document	Upload file by clicking the upload icon. The bibliographic results of	Single file attachment	FLEXIBLE_RECORD.LiteratureSearch.Additional

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	literature searches can be uploaded here in RIS format or as an Excel table containing bibliographic information.		Information.Background.dMaterial.Attachment
Remarks	Indicate the source of the contents of the file and the format type.	Text	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.Background.dMaterial.Remarks
Attached background material			

Link to support material:

Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009
 Further guidance on performing and presenting the literature search
 Inventory of Sources of Scientific Evidence Relevant to EFSA's Risk [Technical Manual for Performing Electronic Literature Searches in Food and Feed Safety](#)

Additional considerations:

The applicant must ensure that terms and conditions asserted by any copyright holder of publications or information submitted to EFSA are fully satisfied. The applicant should consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The applicant remains solely responsible and liable for obtaining all necessary authorisations and rights to use, reproduce and share the publications provided to EFSA

9.2 Change log

Purpose

According to Article 6(2k) of COMMISSION IMPLEMENTING REGULATION (EU) 2020/1740, the renewal dossier shall include a checklist demonstrating that the renewal dossier is complete in view of the uses applied for and indicating which data are new
 To facilitate the automated generation of list of test and study report – 'Previously used'
 All study reports for the active substance and product that were part of the approval or subsequent renewals must be included in the dossier

FLEXIBLE_RECORD.ChangeLog – v.1.0 (Final) [September 2020]

Name	Instructions	Data type	Field path
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General information		Header 1	FLEXIBLE_RECORD.ChangeLog.GeneralInformation
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.ChangeLog.GeneralInformation.field7767
Summary	Provide any additional explanation needed in order to facilitate the compilation of the final list of the tests and studies relied upon and whether the study was already submitted in the framework of national authorizations. 2 See Art.3 of Annex of Regulation No 283/2013 and 284/2013	Rich text area	FLEXIBLE_RECORD.ChangeLog.GeneralInformation.Summary
Change log		Header 1	FLEXIBLE_RECORD.ChangeLog.ChangeLog
Change log entries	Create an entry in the table for each test or study		FLEXIBLE_RECORD.ChangeLog.ChangeLog.ChangeLogEntries
Link to document	Select each of the IUCLID documents included in the dataset	Endpoint reference field	FLEXIBLE_RECORD.ChangeLog.ChangeLog.ChangeLogEntries.LinkToDocument
Status	For each of the documents indicate if the document is 'new', 'previously used' 'obsolete' or 'updated'	Closed list	FLEXIBLE_RECORD.ChangeLog.ChangeLog.ChangeLogEntries.Status
Remark	In the remark indicate for which data point the study has been previously used	Multi-line text	FLEXIBLE_RECORD.ChangeLog.ChangeLog.ChangeLogEntries.Remark
Change log entries			

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Link to support material:

GUIDANCE DOCUMENT ON PREPARING LISTS OF TEST AND STUDY REPORTS ACCORDING TO ARTICLE 60 OF REGULATION (EC) No 1107/2009 (SANCO/12580/2012– rev. 3.1)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_12580.pdf

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1740

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R1740>

10 Classification and labelling

10.1 GHS – Flexible record

Purpose:

Proposals for the classification and labelling of the active substance in accordance with Regulation (EC) No 1272/2008 shall be submitted and justified, including:

- pictograms,
- signal words,
- hazard statements, and precautionary statements.

FLEXIBLE_RECORD.Ghs v6.5 (Final)			
Name	Instructions	Data type	Field path
	Set the confidentiality/regulatory purpose information for each individual record created.	Confidentiality	FLEXIBLE_RECORD.Ghs.DataProtection
General Information		Header 1	FLEXIBLE_RECORD.Ghs.GeneralInformation
Name	When a Substance or a Mixture has more than one classification and labelling record it is recommended to specify a name for each individual record	Text	FLEXIBLE_RECORD.Ghs.GeneralInformation.Name

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	so that they can be easily identified (e.g. 'classification with more/equal 0.1% of substance C' and 'classification with less than 0.1% of substance C').		
Not classified	Select this checkbox if your Substance or Mixture is not classified.	Check box	FLEXIBLE_RECORD.Ghs.GeneralInformation.Not Classified
Implementation	The GHS implementation can be different depending on certain regions (e.g. EU, Japan, Australia). Specify the Implementation by selecting from the drop-down list. If none of the pre-defined items applies, select 'other:'. A text field is then activated next to the list field in which you can enter any freetext. If you wish to record a GHS for another region, add a new block.	Open list	FLEXIBLE_RECORD.Ghs.GeneralInformation.Implementation

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Type of classification	Indicate whether the classification is harmonised or if a self-classification is provided.	Closed list	FLEXIBLE_RECORD.Ghs.GeneralInformation.TypeClassification
Remarks	If necessary provide any additional comments here.	Rich text area	FLEXIBLE_RECORD.Ghs.GeneralInformation.Remarks
Related composition		Header 2	FLEXIBLE_RECORD.Ghs.GeneralInformation.RelatedCompositions
Related composition	This section relates to section 1.2 (Composition – Composition ID). It allows links to be created from a classification to one or more compositions of a substance. Related composition is a repeatable block section. Click the green Plus button to add a new repeatable block. The data entry screen appears and an empty block is now ready to be filled in. Add a new block for each link.	Endpoint reference list	FLEXIBLE_RECORD.Ghs.GeneralInformation.RelatedCompositions.Composition
Classification		Header 1	FLEXIBLE_RECORD.Ghs.Classification

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Physical Hazards		Header 2	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards
Hazard category		Column label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.ReasonForNoClass ification
Explosives		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.Explosives
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.Explosives.Hazard Category
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.Explosives.Hazard Statement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.Explosives.Reason ForNoClassification
Flammable gases and chemically unstable gases		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableGases
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableGases. HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableGases. HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.FlammableGases.

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			ReasonForNoClassification
Aerosols		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableAerosols
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableAerosols.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableAerosols.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableAerosols.ReasonForNoClassification
Chemicals under pressure		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.ChemicalsUnderPressure
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.ChemicalsUnderPressure.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.ChemicalsUnderPressure.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.ChemicalsUnderPressure.ReasonForNoClassification
Oxidising gases		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingGases
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingGases.HazardCategory

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		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingGases.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OxidisingGases.ReasonForNoClassification
Gases under pressure		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.GasesPres
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.GasesPres.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.GasesPres.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.GasesPres.ReasonForNoClassification
Flammable liquids		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableLiquids
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableLiquids.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableLiquids.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableLiquids.ReasonForNoClassification
Flammable solids		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.FlammableSolids

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		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.FlammableSolids.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.FlammableSolids.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.FlammableSolids.ReasonForNoClassification
Self-reactive substances and mixtures		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.SelfReactiveSubstMixt
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.SelfReactiveSubstMixt.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.SelfReactiveSubstMixt.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.SelfReactiveSubstMixt.ReasonForNoClassification
Pyrophoric liquids		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.PyrophoricLiquids
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.PyrophoricLiquids.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHazards.PyrophoricLiquids.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa

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			zards.PyrophoricLiquids. ReasonForNoClassificati on
Pyrophoric solids		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricSolids
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricSolids.H azardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricSolids.H azardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.PyrophoricSolids.R easonForNoClassificatio n
Self-heating substances and mixtures		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.SelfHeatSubstMixt
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.SelfHeatSubstMixt .HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.SelfHeatSubstMixt .HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.SelfHeatSubstMixt .ReasonForNoClassificati on
Substances and mixtures which in contact with water emit flammable gases		Row label	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa zards.SubstMixtWater
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.PhysicalHa

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			zards.SubstMixtWater.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardSubstMixtWater.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardSubstMixtWater.ReasonForNoClassification
Oxidising liquids		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardOxidisingLiquids
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardOxidisingLiquids.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardOxidisingLiquids.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardOxidisingLiquids.ReasonForNoClassification
Oxidising solids		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardOxidisingSolids
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardOxidisingSolids.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardOxidisingSolids.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazardOxidisingSolids.ReasonForNoClassification

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Organic peroxides		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OrganicPeroxides
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OrganicPeroxides.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OrganicPeroxides.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.OrganicPeroxides.ReasonForNoClassification
Corrosive to metals		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.CorMetals
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.CorMetals.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.CorMetals.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.CorMetals.ReasonForNoClassification
Desensitized explosives		Row label	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives.HazardStatement

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		Closed list	FLEXIBLE_RECORD.Ghs.Classification.PhysicalHazards.DesensitizedExplosives.ReasonForNoClassification
Health hazards		Header 2	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ReasonForNoClassification
Acute toxicity - oral		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityOral
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityOral.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityOral.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityOral.ReasonForNoClassification
Acute toxicity - dermal		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityDermal
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityDermal.HazardCategory

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		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityDermal.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityDermal.ReasonForNoClassification
Acute toxicity - inhalation		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityInhalation
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityInhalation.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityInhalation.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.AcuteToxicityInhalation.ReasonForNoClassification
Skin corrosion / irritation		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Irritation
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Irritation.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Irritation.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Irritation.ReasonForNoClassification

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Serious eye damage / eye irritation		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.EyeIrritation
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.EyeIrritation.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.EyeIrritation.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.EyeIrritation.ReasonForNoClassification
Respiratory sensitisation		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.RespiratorySensitisation
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.RespiratorySensitisation.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.RespiratorySensitisation.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.RespiratorySensitisation.ReasonForNoClassification
Skin sensitisation		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.SkinSensitisation
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.SkinSensitisation.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.SkinSensitisation.HazardStatement

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		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.SkinSensitisation.R easonForNoClassificatio n
Aspiration hazard		Row label	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.AspirationHazard
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.AspirationHazard.H azardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.AspirationHazard.H azardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.AspirationHazard.R easonForNoClassificatio n
Reproductive toxicity		Header 3	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ReproductiveToxicit y
Hazard category		Column label	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ReproductiveToxicit y.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ReproductiveToxicit y.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ReproductiveToxicit y.ReasonForNoClassifica tion
Reproductive toxicity		Row label	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ReproductiveToxicit y.ReproductiveToxicity

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		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.ReasonForNoClassification
Specific effect		Text	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.SpecificEffect
Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.ReproductiveToxicity.RouteExposure
Effects on or via lactation		Row label	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.Effects
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.Effects.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity.Effects.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHazards.ReproductiveToxicity

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			y.Effects.ReasonForNoClassification
Germ cell mutagenicity		Header 3	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.ReasonForNoClassification
Germ cell mutagenicity		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell.ReasonForNoClassification
Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.GermCell.GermCell.RouteExposure
Carcinogenicity		Header 3	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHaz

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			ards.Carcinogenicity.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.ReasonForNoClassification
Carcinogenicity		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity.ReasonForNoClassification
Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.Carcinogenicity.Carcinogenicity.RouteExposure
Specific target organ toxicity - single (STOT-SE)		Header 3	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle
			FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHaz

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			ards.ToxicitySingle.Toxicity.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.ReasonForNoClassification
Specific target organ toxicity - single (STOT-SE)		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.ReasonForNoClassification
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.System
Affected organs	Select from the multiple drop-down list the target organ(s) where toxicity	Multi select open list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.AffectedOrgans

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	was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.		
Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.RouteExposure
Specific target organ toxicity - repeated (STOT-RE)		Header 3	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated
			FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.ReasonForNoClassification
Specific target organ toxicity - repeated (STOT-RE)		Row label	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.Toxicity
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.T

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			otoxicity.Toxicity.HazardC ategory
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ToxicityRepeated.T otoxicity.Toxicity.HazardSt atement
		Closed list	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ToxicityRepeated.T otoxicity.Toxicity.ReasonF orNoClassification
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ToxicityRepeated.T otoxicity.Toxicity.System
Affected organs	Select from the multiple drop- down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ToxicityRepeated.T otoxicity.Toxicity.Affected Organs
Route of exposure		Multi select closed list with remarks	FLEXIBLE_RECORD.Ghs. Classification.HealthHaz ards.ToxicityRepeated.T otoxicity.Toxicity.RouteEx posure

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Specific concentration limits		Header 2	FLEXIBLE_RECORD.Ghs.Classification.SpecificConcentrations
			FLEXIBLE_RECORD.Ghs.Classification.SpecificConcentrations.ConcentrationRange
Concentration range (%)		Range (Decimal)	FLEXIBLE_RECORD.Ghs.Classification.SpecificConcentrations.ConcentrationRange.ConcentrationRangeVal
Hazard categories		Multi select closed list	FLEXIBLE_RECORD.Ghs.Classification.SpecificConcentrations.ConcentrationRange.HazardCategories
Environmental hazards		Header 2	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards
Aquatic environment		Header 3	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.ReasonForNoClassification
Hazardous to the aquatic environment (acute / short-term)		Row label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvi

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			ronment.AcuteShortTerm
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.AcuteShortTerm.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.AcuteShortTerm.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.AcuteShortTerm.ReasonForNoClassification
Hazardous to the aquatic environment (long-term)		Row label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.LongTerm
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.LongTerm.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.LongTerm.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.LongTerm.ReasonForNoClassification
M factor		Header 4	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.MFactor
M-Factor acute		Integer	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.MFactor

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			ntalHazards.AquaticEnvironment.MFactor.MFactorAcute
M-Factor chronic		Integer	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.AquaticEnvironment.MFactor.MFactorChronic
Ozone layer		Header 3	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer
Hazard category		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardCategory
Hazard statement		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardStatement
Reason for no classification		Column label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.ReasonForNoClassification
Hazardous to the ozone layer		Row label	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardousOzone
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardousOzone.HazardCategory
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardousOzone.HazardStatement
		Closed list	FLEXIBLE_RECORD.Ghs.Classification.EnvironmentalHazards.OzoneLayer.HazardousOzone.ReasonForNoClassification

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Additional hazard classes		Header 2	FLEXIBLE_RECORD.Ghs.Classification.AdditionalHazard
Additional hazard classes		Text area	FLEXIBLE_RECORD.Ghs.Classification.AdditionalHazard.Classes
Additional hazard statements		Text area	FLEXIBLE_RECORD.Ghs.Classification.AdditionalHazard.Statements
Labelling		Header 1	FLEXIBLE_RECORD.Ghs.Labelling
Signal word		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.SignalWord
Hazard pictogram		Header 2	FLEXIBLE_RECORD.Ghs.Labelling.HazardPictogramBlock
			FLEXIBLE_RECORD.Ghs.Labelling.HazardPictogramBlock.HazardPictogram
Code		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.HazardPictogramBlock.HazardPictogram.Code
Hazard statements		Header 2	FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock
			FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock.HazardStatements
Hazard statement		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock.HazardStatements.HazardStatement
Additional text		Text	FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock.HazardStatements.AdditionalText

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Precautionary statements		Header 2	FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock
			FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock.PrecautionaryStatements
Precautionary statement		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock.PrecautionaryStatement
Additional text		Multi-line text	FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock.PrecautionaryStatements.AdditionalText
Additional labelling requirements		Header 2	FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock
Additional non-GHS hazard statements			FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.LabelingRequirements
Additional non-GHS hazard statement		Closed list	FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.LabelingRequirements.SupplHazardStatement
Additional text		Text	FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.LabelingRequirements.AdditionalText
Additional non-GHS hazard statements			
Additional labelling			FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.AdditionalLabelling
Additional labelling		Text	FLEXIBLE_RECORD.Ghs.Labelling.LabelingRequirementsBlock.AdditionalLabelling

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			ementsBlock.AdditionalLabelling
Additional labelling			
Notes		Header 1	FLEXIBLE_RECORD.Ghs.NotesBlock
			FLEXIBLE_RECORD.Ghs.NotesBlock.Notes
		Closed list	FLEXIBLE_RECORD.Ghs.NotesBlock.Notes.Note

10.2 PBT assessment – Flexible record

Purpose:

A detailed justification and a decision whether the purified active substance is to be classified as persistent, bio accumulative and toxic (PBT) or very persistent and very bio accumulative (vPvB). The decision shall be made in accordance with the criteria laid down in Annex II to Regulation (EC) No 1107/2009. In the recommended guidance a description of scientific principles for the PBT and vPvB assessment is provided.

FLEXIBLE_RECORD.PbtAssessment v5.0 (Final)			
Name	Instructions	Data type	Field path
Administrative data		Header 1	FLEXIBLE_RECORD.PbtAssessment.AdministrativeData
	Set the confidentiality/regulatory purpose information for the study record. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.PbtAssessment.AdministrativeData.DataProtection
Assessed Substance	The chemical for which the PBT/vPvB properties are assessed and recorded can be selected from the following pick list.	Header 1	FLEXIBLE_RECORD.PbtAssessment.AssessedSubstance

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Assessed substance	Select from the pick-list the type of chemical assessed, that is to say: Substance itself: if it is a mono-constituent Constituent: if it is a constituent of the substance in case of multi-constituent and UVCB substances Transformation product: if it is a transformation/degradation product	Closed list	FLEXIBLE_RECORD.PbtAssessment.AssessedSubstance.AssessedSubstance
Reference substance	Assign a reference substance for the substance itself or for the constituent(s).	Entity reference field	FLEXIBLE_RECORD.PbtAssessment.AssessedSubstance.ReferenceSubstance
Composition of assessed substance		Endpoint reference list	FLEXIBLE_RECORD.PbtAssessment.AssessedSubstance.AssessedSubstanceCompo
PBT status of the assessed substance		Closed list	FLEXIBLE_RECORD.PbtAssessment.AssessedSubstance.PBTStatusOfTheAssessedSubstance
Remark for assessed substance	If necessary provide any additional comments here. This field can be used for example in order to identify transformation products as for these chemicals it is not possible to assign a reference substance.	Multi-line text	FLEXIBLE_RECORD.PbtAssessment.AssessedSubstance.AssessedSubstanceRemark
Results of detailed PBT / vPvB assessment	The structure of this section is built in such a way that the end-user can report evidence that the chemical assessed	Header 1	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed

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	is: - not PBT or not vPvB or - is PBT and/or vPvB		
Persistence		Header 2	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence
Evidence of non-P / non-vP properties	If the chemical does not fulfil the P and/or vP criteria then at least one of the following blocks should be filled in. For more information on the information to be included in the different fields please refer to the relevant guidance for the respective chemical regulatory programme.	Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence
Screening criteria	Click the Add button to open the block for screening criteria. Select the first check box if evidence of ready biodegradation based on testing can be provided e.g. OECD 301 series. If needed you can provide more information about the testing in the remark field. Select the second check box if you have evidence of degradation for your chemical based on other screening tests (e.g. inherent biodegradability test, enhanced ready	Header 4	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.ScreeningCriteria

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	biodegradability). If needed you can provide more information about the test(s) in the remark field.		
Not P and not vP based on: readily biodegradable		Check box	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.ScreeningCriteria.NotPreadilyBiodegradable
Remark		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.ScreeningCriteria.NotPreadilyBiodegradableRemark
Not P and not vP based on: other screening test(s) (e.g. enhanced ready biodegradability, inherent biodegradability test) under valid conditions		Check box	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.ScreeningCriteria.NotPOtherTest
Remark		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.ScreeningCriteria.NotPOtherTestRemark
Criteria based on Annex XIII of REACH	Click the Add button to open the block for criteria based on Annex XIII of REACH. In this block of information it is possible to conclude if the chemical is 'not P and not vP' or 'P but not vP' based on a comparison of half-lives obtained in different media with the criteria for persistence of REACH Annex XIII.	Header 4	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased

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	<p>Select the relevant check box 'not P and not vP' or 'P but not vP' for your chemical based for instance on the outcome of tests on simulation of biodegradation (e.g. OECD 307, 308 and 309). If one of the check boxes is ticked it is not enough to fill in only one justification field. All the text fields should be filled in accordingly as a chemical can be concluded as P or not vP only based on the fulfilment of all criteria (e.g. if the tick box 'P but not vP' is ticked then a justification has to be filled in for marine, fresh- or estuarine water, for marine, fresh- or estuarine sediment and for soil).</p>		
<p>Not P and not vP based on</p>	<p>Select the relevant check box 'not P and not vP' or 'P but not vP' for your chemical based for instance on the outcome of tests on simulation of biodegradation (e.g. OECD 307, 308 and 309). If one of the check boxes is ticked it is not enough to fill in only one justification field. All the text</p>	<p>Check box</p>	<p>FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased.NotPBasedOn</p>

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	fields should be filled in accordingly as a chemical can be concluded as P or not vP only based on the fulfilment of all criteria (e.g. if the tick box 'P but not vP' is ticked then a justification has to be filled in for marine, fresh- or estuarine water, for marine, fresh- or estuarine sediment and for soil).		
T_{1/2} ≤ 60 days in marine water		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased.WaterMarine60
and T_{1/2} ≤ 40 days in fresh- or estuarine water		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased.WaterFresh40
and T_{1/2} ≤ 180 days in marine sediment		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased.SedimentMarine180
and T_{1/2} ≤ 120 days in fresh- or estuarine sediment		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased.SedimentFresh120
and T_{1/2} ≤ 120 days in soil		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased.Soil120
P but not vP based on		Check box	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased.PNotvPBasedOn
T_{1/2} ≤ 60 days in marine, fresh- or estuarine water		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased.Water60
and T_{1/2} ≤ 180 days in marine,		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Ev

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fresh- or estuarine sediment and T_{1/2} ≤ 180 days in soil			idence.PersistenceAnnexBased.Sediment180
		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.PersistenceAnnexBased.Soil180
Other evidence of non-P / non-vP properties	Click the Add button to open the remark block for other evidence of non-P/non-vP properties. Such evidence can be for instance abiotic degradation data (e.g. hydrolysis, direct and indirect photodegradation).	Header 4	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.OtherEvidence
Remark		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.Evidence.OtherEvidence.Remark
Further information for the PBT assessment is necessary		Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.PersistenceFurtherInfo
Remark	Please refer to the general introduction of section Results of detailed PBT/vPvB assessment.	Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.PersistenceFurtherInfo.FurtherInfoRemark
Evidence of P or vP properties		Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.PersistenceEvidence
Remark	You can report in this field any evidence of persistency for the chemical assessed e.g. based on experimental results, valid estimated results (e.g. Q(S)ARs) and/or any other relevant	Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.PersistenceEvidence.EvidenceRemark

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	information. For more information on the information to be included in the different fields please refer to the relevant guidance for the respective chemical regulatory programme thereof (e.g. REACH Guidance on information requirements and Chemical Safety Assessment, PBT assessment).		
Conclusion		Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.PersistenceConclusion
Conclusion on P / vP properties	Select from the pick-list the appropriate conclusion for the P assessment regarding the chemical assessed and considering all information gathered for the criterion. If needed, add in the free text field below the pick-list any additional comments or a short summary of the P assessment.	Closed list	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.PersistenceConclusion.ConclusionOnPvP
Remark		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Persistence.PersistenceConclusion.Remark
Bioaccumulation		Header 2	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation
Evidence of non-B / non-vB properties	If the chemical does not fulfil the B and/or vB criteria	Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB

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	then at least one of the following blocks should be filled in. For more information on the information to be included in the different fields please refer to the relevant guidance for the respective chemical regulatory programme thereof (e.g. REACH Guidance on information requirements and Chemical Safety Assessment PBT assessment).		
Screening criteria	Click the Add button to open the block for screening criteria. Select the check box 'Not B and not vB' if log Kow of the chemical assessed is below 4.5. If needed, you can provide more information about the log Kow value and its determination in the remark field below.	Header 4	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB.BioScreening
Not B and not vB based on: Log Kow ≤ 4.5		Check box	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB.BioScreening.NotBBasedOnLogKow
Remark		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB.BioScreening.NotBRemark
Criteria based on Annex XIII of REACH	Click the Add button to open the block for criteria based on	Header 4	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation

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	Annex XIII of REACH. In this block of information it is possible to conclude if the chemical is 'not B and not vB' or 'B but not vB' based on a comparison of the valid BCF value(s) available with the bioaccumulation criteria of Annex XIII.		on.EvidenceNonB.BioAnnexBased
Not B and not vB based on: BCF ≤ 2,000 L/kg	Select the relevant check box 'not B and not vB' or 'B but not vB' for your chemical depending on the outcome of bioconcentration or bioaccumulation studies with aquatic organisms e.g. OECD 305. If needed, you can provide detailed information about the test in the remark field below.	Check box	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB.BioAnnexBased.NotBBCF200
Remark		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB.BioAnnexBased.NotBBCF200Remark
B but not vB based on: 2,000 < BCF ≤ 5,000 L/kg	Select the relevant check box 'not B and not vB' or 'B but not vB' for your chemical depending on the outcome of bioconcentration or bioaccumulation studies with aquatic organisms e.g. OECD 305. If needed, you can	Check box	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB.BioAnnexBased.BNotVBBCF5000

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	provide detailed information about the test in the remark field below.		
Remark		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB.BioAnnexBased.BNotVBBCF5000Remark
Other evidence of non-B / non-vB properties	Click the Add button to open the remark block for other evidence of non-B/non-vB properties (e.g. biomagnification information, toxicokinetic studies with mammals)).	Header 4	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB.BioOtherEvidence
Remark		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.EvidenceNonB.BioOtherEvidence.OtherEvidenceRemark
Further information for the PBT assessment is necessary		Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.BioFurtherInfo
Remark	Please refer to the general introduction of section Results of detailed PBT/vPvB assessment.	Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.BioFurtherInfo.PBTInfoRemark
Evidence of B or vB properties		Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.BioEvidence
Remark	You can report in this field any evidence of persistency for the chemical assessed e.g. based on experimental results, valid estimated results (e.g. Q(S)ARs) and/or any other relevant	Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.BioEvidence.BioEvidenceRemark

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	information. For more information on the information to be included in the different fields please refer to the relevant guidance for the respective chemical regulatory programme thereof (e.g. REACH Guidance on information requirements and Chemical Safety Assessment,; PBT assessment)		
Conclusion		Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.BioConclusion
Conclusion on B / vB properties	Select from the pick-list the appropriate conclusion for the B assessment regarding the chemical assessed and considering all information gathered for the criterion. If needed, add in the free text field below the pick-list any additional comments or a short summary of the B assessment	Closed list	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.BioConclusion.ConclusionOnB
Remark	If needed, add in the free text field below the pick-list any additional comments or a short summary of the B assessment.	Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Bioaccumulation.BioConclusion.BioConclusionRemark
Toxicity		Header 2	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity

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<p>Evidence of non-T properties</p>	<p>If the chemical does not fulfil the T criterion then at least one of the following blocks should be filled in. For more information on the information to be included in the different fields please refer to the relevant guidance for the respective chemical regulatory programme thereof (e.g. REACH Guidance on information requirements and Chemical Safety Assessment; PBT assessment)</p>	<p>Header 3</p>	<p>FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.EvidenceOfNonT</p>
<p>Criteria based on Annex XIII of REACH</p>	<p>Click the Add button to open the block for criteria based on Annex XIII of REACH. In this block of information it is possible to conclude if the chemical is 'not T' based on a comparison of chronic toxicity data and classification information available for the chemical with the toxicity criteria of Annex XIII.</p>	<p>Header 4</p>	<p>FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.EvidenceOfNonT.ToxicityAnnexBased</p>
<p>Not T based on:</p>	<p>Select the check box 'not T' if the chemical is not toxic based on long term toxicity for marine or freshwater organisms and that</p>	<p>Check box</p>	<p>FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.EvidenceOfNonT.ToxicityAnnexBased.NotT</p>

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	<p>it is not classified for carcinogenicity, mutagenicity, reprotoxicity or for chronic toxicity according to the regulation 1272/2008 (CLP regulation) or the DSD. If the check box 'not T' is ticked then it is not enough to fill in only one justification field. All the text fields should be filled in accordingly as a chemical can be concluded as not T based only on the fulfilment of all criteria (e.g. if the check box 'not T' is ticked then a justification has to be filled in for long term toxicity for marine or freshwater organisms and for long term toxicity for mammals (according to the CLP Regulation or the DSD)).</p>		
<p>EC10 or NOEC ≥ 0.01 mg/L for marine / freshwater organisms (long-term toxicity)</p>		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.EvidenceOfNonT.ToxicityAnnexBased.ToxicityLongTerm
<p>and substance is not classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2),</p>		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.EvidenceOfNonT.ToxicityAnnexBased.SubstanceNotClassified

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<p>or toxic for reproduction (category 1, 2 or 3) according to Directive 67/548/EEC or carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) according to Regulation EC No 1272/2008</p>			
<p>and no other evidence of chronic toxicity, as identified by the classifications T, R48 or Xn, R48 according to Directive 67/548/EEC or specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008</p>		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.EvidenceOfNonT.ToxicityAnnexBased.NoOtherEvidence
<p>Other evidence of non-T properties</p>	Click the Add button to open the remark block for other evidence of non-T properties (e.g. chronic data on birds).	Header 4	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.EvidenceOfNonT.ToxicityOtherEvidence
<p>Remark</p>		Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.EvidenceOfNonT.ToxicityOtherEvidence.OtherEvidenceRemark

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Further information for the PBT assessment is necessary		Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.ToxicityFurtherInfo
Remark	Please refer to the general introduction of section Results of detailed PBT/vPvB assessment.	Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.ToxicityFurtherInfo.ToxicityFurtherInfoRemark
Evidence of T properties		Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.ToxicityEvidence
Screening criteria: L(E)C50 < 0.01 mg/L	Select this check box if the chemical is toxic based on an acute test.	Check box	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.ToxicityEvidence.ToxicityEvidenceScreening
other evidence	Select this check box if the chemical is toxic based on e.g. experimental results (chronic test), valid estimated results (e.g. (Q)SARs) or any other relevant information.	Check box	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.ToxicityEvidence.ToxicityOtherEvidence
Remark	If needed, you can report in this field any evidence of toxicity for the chemical assessed based on the above information. This text field has to be filled in only when the check box 'other evidence' is ticked.	Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.ToxicityEvidence.ToxicityEvidenceRemark
Conclusion		Header 3	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.ToxicityConclusion
Conclusion on T properties	Select from the pick-list (see screenshot below) the appropriate conclusion for the T assessment	Closed list	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.ToxicityConclusion.Conclusion

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	regarding the chemical assessed and considering all information gathered for the criterion.		
Remark	If needed, add in the free text field below the pick-list any additional comments or a short summary of the T assessment.	Multi-line text	FLEXIBLE_RECORD.PbtAssessment.ResultsDetailed.Toxicity.ToxicityConclusion.ToxicityConclusionRemark

11 Summary and evaluation

11.1 Assessment from other authorities

Purpose:

Provide information on previous assessments of the active substance, as a pesticide or under other regulatory processes, both within Europe and outside of Europe.

Listing of EU MRLs (Document E1)

List of MRLs established in exporting countries or in non-EU OECD countries (Document E2)

FLEXIBLE_RECORD.AssessmentOtherAuthorities – v 1.3 (Final) [October 2020]

Name	Instructions	Type	Field Path
Administrative data	See Administrative data	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdministrativeDataSummary
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdministrativeDataSummary.DataProtection
Assessments in Europe	In this section, provide information on previous or ongoing evaluations in Europe.	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope
Biocide	Indicate if this active substance has been or is being assessed under the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.Biocide

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Veterinary medicine	Indicate if this active substance has been or is being assessed under the veterinary medicinal products Regulation (EU) 2019/6. Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.VeterinaryMedicine
Other product safety assessments	In this section provide information on previous or ongoing evaluations in Europe under regulations other than Biocides or Veterinary Medicines		FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.OtherProductSafetyAssessments
Evaluation	If this active substance has been or is being assessed under any other product or food safety regulations indicate the context of the evaluation.	Open list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.OtherProductSafetyAssessments.Evaluation
Status	Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.OtherProductSafetyAssessments.Status
Other product safety assessments			
Existing residue definitions		Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues
Monitoring purposes (plant)	<p>Check the current existing RD in the EU MRL data base.</p> <p>The field refers to the enforcement residue definition of plant commodity/ies for which the MRL application is submitted. An EU Pesticides data base could be consulted</p> <p>If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.MonitoringPurposesPlant
Risk assessment (plant)	The field refers to the risk assessment residue definitions for plant commodity/ies for which the MRL application is submitted.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.RiskAssessmentPlant

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	<p>If different risk assessment residue definitions are set in different plant commodities under consideration, this shall be indicated.</p> <p>If for processed commodities residue definitions differ from residue definitions in raw agricultural commodity (RAC), this shall be indicated.</p> <p>If for rotational crops the residue definition differs from the residue definition in primary crops, this shall be indicated.</p> <p>Available in EFSA ccl and Registration reports</p>		
Monitoring purposes (animal)	<p>The field refers to the enforcement residue definitions for animal commodity/ies for which the MRL application is submitted. An EU Pesticides data base could be consulted</p> <p>If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.</p> <p>Please check the current existing RD in the EU MRL data base.</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.MonitoringPurposesAnimal
Risk assessment (animal)	<p>The field refers to the risk assessment residue definitions for animal commodity/ies for which the MRL application is submitted.</p> <p>If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated.</p> <p>Available in EFSA ccl and Registration reports</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.RiskAssessmentAnimal
Remarks	<p>Any comment on the existing RD for risk assessment (e.g. provisional, clarify the source, data gaps, ...)</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.Remarks
EFSA paramCode			FLEXIBLE_RECORD.AssessmentOtherAuthorities.Asses

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			smentsEurope.ExistingResidues.EfsaParamCode
RD paramCode	Enter one or more EFSA param codes to identify the substance/s which comprise the residue definition for monitoring purpose (as used for reporting pesticide residue monitoring data) EFSA paramCodes can be downloaded or accessed by the EFSA catalogue browser application	Text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.EfsaParamCode.RdParamCode
EFSA paramCode Existing MRL			
EU MRL	List the existing EU MRLs for this active substance	Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl
Commodity	Select the commodity The picklist comprises commodities as listed in Part A of Annex I to Reg. 396/2005 and in addition feed commodities.	Multi select closed list with remarks	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl.Commodity
MRL value	Enter the MRL value in mg/kg	Unit measure with Closed List (Decimal)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl.MrlValue
Residue definition monitoring	Enter the enforcement residue definition in the commodity/ies for the MRL	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl.ResidueMonitoring
Remarks	Any comment on the existing MRL (provisional, confirmatory data required..)	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl.Remarks
EU MRL			
Assessments outside Europe	In this section provide information on previous or ongoing evaluations outside of Europe	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope

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Biocide	Indicate if this active substance has been or is being assessed for use as a biocide outside of Europe. Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.Biocide
Veterinary medicine	Indicate if this active substance has been or is being assessed for use as a veterinary medicine outside of Europe Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.VeterinaryMedicine
Other product safety assessments	In this section provide information on previous or ongoing evaluations outside Europe under regulations other than Biocides or Veterinary Medicines		FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.OtherProductSafetyAssessments
Evaluation	If this active substance has been or is being assessed under any other product or food safety regulations indicate the context of the evaluation.	Open list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.OtherProductSafetyAssessments.Evaluation
Status	Indicate if this active substance has been or is being assessed under any other product or food safety regulations. If yes provide details on the nature and status of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.OtherProductSafetyAssessments.Status
Other product safety assessments			
Existing residue definitions	Enter the enforcement residue definitions for the MRL in the exporting country if they differ from those listed above	Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues
Monitoring purposes (plant)	The field refers to the enforcement residue definition in the exporting country for plant commodity'ies for which the MRL application is submitted. If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.MonitoringPurposesPlant

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Risk assessment (plant)	<p>The field refers to the risk assessment residue definition in the exporting country in the plant commodity for which the MRL application is submitted.</p> <p>If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated.</p> <p>If the MRL application is submitted to account for residues in rotational crops and the residue definition in rotational crops differs from the residue definition in primary crops, this shall be indicated.</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.RiskAssessmentPlant
Monitoring purposes (animal)	<p>The field refers to the enforcement residue definition in the exporting country for the animal commodity/ies for which the MRL application is submitted.</p> <p>If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.MonitoringPurposesAnimal
Risk assessment (animal)	<p>The field refers to the risk assessment residue definition in the exporting country for the animal commodity for which the MRL application is submitted.</p> <p>If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated.</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.RiskAssessmentAnimal
Remarks	<p>Any comment on the existing RD for risk assessment (e.g. provisional, clarify the source, data gaps, ...)</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.Remarks
Existing MRL in the exporting country		Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries
Exporting country MRL			FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl

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Country	Select the exporting country from the list	Multi select open list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Country
Commodity	<p>The commodity plant parts which were analysed for and for which results should be reported in this table.</p> <p>The picklist comprised commodities as listed in Part A of Annex I to Reg. 396/2005 and in addition feed commodities. ONLY in case the tested commodity is not present in the picklist choose "other" and enter manually..</p>	Multi select open list with remarks	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Commodity
MRL value	<p>If MRL setting processes are established in exporting countries.</p> <p>If MRL setting processes are not established in exporting countries, specify if Codex residue limit (CXL) is applicable.</p> <p>If there are no CXL and no MRL in the exporting country, report 'not relevant' and specify the reason in remark box.</p>	Unit measure with Closed List (Decimal)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.MrlValue
Residue definition monitoring	Enter the enforcement residue definition of plant commodity/ies for the MRL	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.ResidueMonitoring
Remarks	<p>Any additional remark on the MRL in the exporting country.</p> <p>If MRL setting processes are not established in exporting countries, specify if Codex residue limit (CXL) is applicable.</p> <p>If no CXL and no MRL in the exporting country, report 'not relevant' and specify the reason in remark box.</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Remarks
Exporting country MRL			
Additional information	This section is only relevant for MRL applications	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation

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Evidence of registration in the exporting country	Please confirm with this checkbox that the evidence of the registration in the exporting country and, if available, the registered use pattern in the exporting country were attached.	Check box	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.RegistrationInExportingCountry
Evidence of registration in the exporting country (remark)	Clarification should be given in remark field if no evidence can be provided.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.RegistrationInExportingCountryRemark
Evidence of registration in the exporting country attached	Upload attachments with evidence of registration in the exporting country (these attachments will be published and should not contain confidential information)	Attachments list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.RegistrationInExportingCountryAttachment
Registered use pattern in the exporting country	Please confirm with this checkbox that the registered use pattern has been entered in the Good agricultural practices (GAP) document has been completed. Product Section 2	Attachments list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.RegistrationInExportingCountryUsePattern
Legislation in the exporting country concerning the MRL	Please confirm with this checkbox that the Legislation in the exporting country concerning the MRL attached.	Check box	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.LegislationInExportingCountry
Legislation in the exporting country concerning the MRL (remark)	Clarification should be given if no MRLs are established in the originating country.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.LegislationExportingCountryRemark
Legislation in the exporting country concerning the MRL attached	Upload copies of the Legislation in the exporting country concerning the MRL	Attachments list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.LegislationExportingCountryAttachment

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11.2 Other reports

<p>Purpose Summarise the overall conclusions for the substance or mixture Provide a place to upload files or reports which could not be attached in other sections but are used to support the evaluation.</p>

FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP – v.1.1.1 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	See administrative data	Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdministrativeDataSummary
	Use this field to set flags for confidentiality and regulatory purpose(s). Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdministrativeDataSummary.DataProtection
Reports and administrative information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo
Reports and administrative information			FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo
Type of report	Indicate the type of document that has been uploaded e.g. 'Document C Existing or proposed labels'	Multi-line text	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.TypeOfReport
Attached document	If the file or document uploaded in the 'Attach one or more documents including the sanitised version of the document' contains redacted information	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.AttachedDocument

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	upload the original version in this field		
Attached (sanitised) document for publication	<p>Upload sanitised version of files or documents which could not be uploaded in other sections of the dossier. This would include</p> <p>'Document C Existing or proposed labels'</p> <p>'Document G Permission of each formulant in accordance with EU legislation'</p> <p>'Document I Other data on the formulants'</p> <p>Documents M, N and L - report generator should be used to create these documents when the appropriate report format (ftl file) is available</p>	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.SanitisedDocument
Reports and administrative information			
Other references (including SDS)	<p>Link to other reports not referenced in the endpoint study records needed to support the assessment. The bibliographic information should be completed and the PDF uploaded in the literature reference entity</p>	Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS

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	This would include 'Safety datasheets' 'Scientific opinions of national/international regulatory bodies'		
References		Literature reference list	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS.References
Additional information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation
Additional information	Overall summary of the main conclusions for the substance or mixture can be entered here	Rich text area	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation

Additional considerations

The applicant must ensure that terms and conditions asserted by any copyright holder of publications or information submitted to EFSA are fully satisfied. The applicant should consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The applicant remains solely responsible and liable for obtaining all necessary authorisations and rights to use, reproduce and share the publications provided to EFSA

Referenced entities

Reference substance

Purpose

Chemicals: Identity of the active substance – ISO common name and synonyms, Chemical name in accordance with IUPAC and CA nomenclature, CAS Reg number EC number, molecular and structural formula, molar mass

Microorganisms: Identity of the microorganism – Name, taxonomy, species description and strain characterisation

The Reference substance inventory gives the possibility to use the same information for the same chemical/microorganism identity avoiding duplicate data entry and to ensure that the data is centrally managed and updated. Each reference substance can be linked to an unlimited number of substance or mixture datasets.

Reference substance/s can be exported and shared from the Reference substance entity manager

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Name	Instructions	Type	Field Path
	Set confidentiality and regulatory program flags.	Confidentiality	REFERENCE_SUBSTAN CE.DataProtection
Reference substance name	Name of substance, microorganism, metabolite, residue, impurity or other substance included in the dossier For the active substances the ISO common name or proposed ISO name should be reported	Multi-line text	REFERENCE_SUBSTAN CE.ReferenceSubstance Name
IUPAC name	IUPAC name (Note that, if a name following the IUPAC nomenclature cannot be derived, you should still provide a name defining the chemical nature of the substance). For microorganisms the scientific name (species and strain) should be reported in this field.	Multi-line text	REFERENCE_SUBSTAN CE.IupacName
Description	Specify any additional information relevant for the description of the reference substance in this field For microorganisms the taxonomic information family, genus, species, strain, serotype, pathovar or any other denomination relevant to the micro-organism should be reported. In addition it should be indicated whether the microorganism - is indigenous or non-indigenous at the species level to the intended area of application - is a wild type - is a spontaneous or induced mutant - has been modified using techniques described in Part 2 of Annex IA and in Annex IB to Directive 2001/18/EC (*) of the European Parliament and of the Council	Text template	REFERENCE_SUBSTAN CE.Description

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Inventory	Can be used to select existing substances with pre-assigned EC numbers.	Header 1	REFERENCE_SUBSTANCE.Inventory
Inventory number	Can be used to select existing substances with pre-assigned EC numbers.	Entity reference list	REFERENCE_SUBSTANCE.Inventory.InventoryEntry
No inventory information available - Justification	Not relevant for EU PPP	Open list with remarks	REFERENCE_SUBSTANCE.Inventory.InventoryEntryJustification
CAS number	CAS Registry Number	Text	REFERENCE_SUBSTANCE.Inventory.CASNumber
CAS name	CAS name	Multi-line text	REFERENCE_SUBSTANCE.Inventory.CASName
CIPAC number	CIPAC number		
Synonyms		Header 1	REFERENCE_SUBSTANCE.Synonyms
Synonyms	List any synonyms for the substance For microorganisms alternative names should be added in the table and the accession number/s from internationally recognised culture collections EFSA paramCode should be added in the table		REFERENCE_SUBSTANCE.Synonyms.Synonyms
	Set confidentiality and regulatory program flags	Confidentiality	REFERENCE_SUBSTANCE.Synonyms.Synonyms.DataProtection
Identifier	Select the type of identifier you wish to provide using the picklist. If none of pre-defined items apply, select 'other:'. A text field is then activated next to the list field in which you can specify the type of identifier you wish to provide.	Open list	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Identifier
Identity	Enter here the identity (name, number, code) corresponding to the identifier type selected.	Text area	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Name

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Remarks		Text	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Remarks
Synonyms			
Molecular and structural information		Header 1	REFERENCE_SUBSTANCE.MolecularStructuralInfo
		Confidentiality	REFERENCE_SUBSTANCE.MolecularStructuralInfo.DataProtection
Molecular formula	Molecular formula (if a molecular formula cannot be derived from the reference substance, a justification should be indicated in the Remarks field at the bottom of the section)	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.MolecularFormula
Molecular weight	Molecular weight should be reported as a single numeric value	Range (Decimal)	REFERENCE_SUBSTANCE.MolecularStructuralInfo.MolecularWeightRange
SMILES notation	The SMILES notation should be in the canonical form https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.SmilesNotation
InChI	The IUPAC international chemical identifier https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.InChI
Structural formula	The structural formula for the active substance https://chem.nlm.nih.gov/chemidplus/structure3D/viewer/ ChemSketch, ChemDraw	Image	REFERENCE_SUBSTANCE.MolecularStructuralInfo.StructuralFormula
Remarks	See molecular formula	Text area	REFERENCE_SUBSTANCE.MolecularStructuralInfo.Remarks
Chemical structure files	Upload chemical structures files (both machine readable and an image file)		REFERENCE_SUBSTANCE.MolecularStructuralInfo.ChemicalStructureFiles

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	For machine readable files the format should be .sk2 or .cdx or .mol For image files the format should be jpg or png		
Structure file		Single file attachment	REFERENCE_SUBSTANCE.MolecularStructuralInfo.ChemicalStructureFiles.StructureFile
Remarks on structure file		Text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.ChemicalStructureFiles.RemarksChemStruct
Chemical structure files			
Related substances	Not relevant for EU PPP	Header 1	REFERENCE_SUBSTANCE.RelatedSubstances
			REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances
Identifier		Open list	REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances.Identifier
Identity		Text area	REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances.Identity
Remarks		Text	REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances.Remarks
Relation		Open list	REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances.Relation
Group / category information		Multi-line text	REFERENCE_SUBSTANCE.RelatedSubstances.GroupCategoryInfo

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Legal entity (including contact entity)

Purpose:

Submissions require a Legal entity which has to be defined including contact details prior to submission. A Legal Entity (LE) may represent anything between a complex business structure and a simple organised business, for example, a corporation, a company, or a single person. LEs are identified by their name, universally unique identifier (UUID), address, country, and general contact information. You can create a LEO via ECHA accounts

It is used for functionalities where it is critical to ensure uniqueness of the Legal Entity information e.g. for specifying data ownership or identify your own company/organisation.

If you are installing a local version of IUCLID, a LEO will have been created during the installation of the client version of IUCLID. You can then export it from IUCLID and import it to you ECHA account. If you have an ECHA account and define a LEO there, you can export the LEO and import it to your own local IUCLID installation.

You can add more legal entities within the IUCLID application via the inventory.

Field name	Instructions	Path
General information		LEGAL_ENTITY.GeneralInfo
Legal Entity name	Name of the legal entity i.e. Company name	LEGAL_ENTITY.GeneralInfo.LegalEntityName
Legal entity type	Select one legal entity type from the dropdown menu. If other, please include an explanation in the free text field below.	LEGAL_ENTITY.GeneralInfo.LegalEntityType
Remarks	Any additional information on the legal entity, if relevant	LEGAL_ENTITY.GeneralInfo.Remarks
Other names	Other names can be specified and if needed these names can be marked as confidential	LEGAL_ENTITY.GeneralInfo.OtherNames
Address	See Confidentiality Requests	LEGAL_ENTITY.GeneralInfo.ContactAddress.DataProtection
Address 1	Street address of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Address1
Address 2	Secondary address, if relevant	LEGAL_ENTITY.GeneralInfo.ContactAddress.Address2

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Postal Code	Postal code of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Postal
Town	Town of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Town
Region/State	Region/State of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Region
Country	Select the country in which the legal entity is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	LEGAL_ENTITY.GeneralInfo.ContactAddress.Country
Phone	Phone number of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Phone
Fax	Fax number of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Fax
Email	Email address of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Email
Website	Legal entity website	LEGAL_ENTITY.GeneralInfo.ContactAddress.WebSite
Identifiers	<p>Optional: Other identifiers can be reported. Legal entity identifiers, Regulatory programme identifiers, and Other IT system identifiers. Each type contains a menu from which relevant sub-types of identifier can be selected. For example, Legal entity has an option for DUNS (Data Universal Numbering System for identification of a Legal Entity).</p> <p>Click on New Item and set values. See Confidentiality Requests.</p>	LEGAL_ENTITY.Identifiers
Contact information	An address can be defined for a contact person of the Legal	LEGAL_ENTITY.ContactInfo

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	entity and links can be made to one or more Contact entities	
Contact Person	This can be managed in the Contact entity manager	
General information		CONTACT.GeneralInfo
Contact type	Select one contact type from the dropdown menu. If other, enter the appropriate contact type in the free text field below.	CONTACT.GeneralInfo.ContactType
Last name	Last name of the contact person. Note that this field is mandatory	CONTACT.GeneralInfo.LastName
First name	First name of the contact person.	CONTACT.GeneralInfo.FirstName
Organisation	Name of the Organisation. Note that this field is mandatory	CONTACT.GeneralInfo.Organisation
Department	e.g. Scientific Department	CONTACT.GeneralInfo.Department
Title	Title of the contact person (e.g. Mr.).	CONTACT.GeneralInfo.Title
Phone	Phone number of the contact person	CONTACT.GeneralInfo.Phone
Mobile	Mobile phone number of the contact person	CONTACT.GeneralInfo.Mobile
Fax	Fax number of the contact person	CONTACT.GeneralInfo.Fax
Email	Email address of the contact person	CONTACT.GeneralInfo.Email
Address 1	Street address of the contact person	CONTACT.GeneralInfo.Address1
Address 2	Secondary address, if relevant	CONTACT.GeneralInfo.Address2
Postal Code	Postal code of the street address of the contact person	CONTACT.GeneralInfo.Postal
Town	Town of the contact person	CONTACT.GeneralInfo.Town
Region/State	Region/State of the contact person	CONTACT.GeneralInfo.Region
Country	Select the country in which the contact person is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	CONTACT.GeneralInfo.Country
Remarks	Any additional information, if relevant	CONTACT.GeneralInfo.Remarks

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Links to support material:

<https://echa.europa.eu/support-echa-accounts-and-eu-login>

https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_html_en.pdf/9d01cb53-902d-dbb6-fb00-fa141688c395

https://echa.europa.eu/documents/10162/21721613/echa_accounts_en.pdf

<https://www.youtube.com/watch?v=4JGsQUbGYqw>

Contact entity

Name	Instructions	Type	Field path
General information		Header 1	CONTACT.GeneralInfo
Contact type	Select one contact type from the dropdown menu. If other, enter the appropriate contact type in the free text field below.	Open list	CONTACT.GeneralInfo.ContactType
Last name	Last name of the contact person. Note that this field is mandatory	Text	CONTACT.GeneralInfo.LastName
First name	First name of the contact person.	Text	CONTACT.GeneralInfo.FirstName
Organisation	Name of the Organisation. Note that this field is mandatory	Text	CONTACT.GeneralInfo.Organisation
Department	e.g. scientific department.	Text	CONTACT.GeneralInfo.Department
Title	Title of the contact person (e.g. Mr.).	Text	CONTACT.GeneralInfo.Title
Phone	Phone number of the contact person.	Text	CONTACT.GeneralInfo.Phone
Mobile	Mobile phone number of the contact person.	Text	CONTACT.GeneralInfo.Mobile
Fax	Fax number of the contact person.	Text	CONTACT.GeneralInfo.Fax
Email	Email address of the contact person.	Text	CONTACT.GeneralInfo.Email
Address 1	Street address of the contact person.	Text	CONTACT.GeneralInfo.Address1

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Address 2	Secondary address, if relevant	Text	CONTACT.GeneralInfo.Address2
Postal code	Postal code of the street address of the contact person.	Text	CONTACT.GeneralInfo.Postal
Town	Town of the contact person.	Text	CONTACT.GeneralInfo.Town
Region / state	Region/State of the contact person.	Text	CONTACT.GeneralInfo.Region
Country	Select the country in which the contact person is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	Open list	CONTACT.GeneralInfo.Country
Remarks	Any additional information, if relevant.	Text area	CONTACT.GeneralInfo.Remarks

Literature reference

<p>Purpose</p> <p>Storage of bibliographic metadata with attached documents including full study reports and published scientific papers</p> <p>Linking studies to the Notification of Studies Database</p> <p>Used as the data source in OECD harmonised templates and DOMAIN Endpoint Study Records</p> <p>It is important to create a Literature reference for all studies used as evidence in the dossier. This would also include all relevant studies selected for full-text assessment identified from a literature search (when required).</p>

Name	Instructions	Type	Field Path
General information		Header 1	LITERATURE.GeneralInfo
Reference Type	<p>Select 'study report' for a full study report used as a data source for an endpoint study record.</p> <p>Select 'published' for relevant studies identified from a literature search to address data requirements</p> <p>The other reference types can also be used</p>	Open list	LITERATURE.GeneralInfo.LiteratureType

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Title	Title of the study report, publication or other report type	Text	LITERATURE.GeneralInfo.Name
Author	Author names for the study. These will be redacted from the published dossier for unpublished toxicology studies.	Multi-line text	LITERATURE.GeneralInfo.Author
Year	The year the report must be reported (this is used for sorting and filtering)	Integer	LITERATURE.GeneralInfo.ReferenceYear
Bibliographic source	For published studies information on the journal and edition should be completed. This should include the DOI (Digital Object Identifier)	Text	LITERATURE.GeneralInfo.Source
Testing facility	For study reports information on the testing facility should be completed. This information will not be published for studies involving tests on vertebrate animals.	Text	LITERATURE.GeneralInfo.TestLab
Report no.	Specify the report number allocated by the testing laboratory. This information will not be published for studies involving tests on vertebrate animals.	Text	LITERATURE.GeneralInfo.ReportNo
Study sponsor	Information on the source of funding of the study can be provided	Text	LITERATURE.GeneralInfo.CompanyOwner
Study no.	Report the company identifier, if it differs from the laboratory report number	Text	LITERATURE.GeneralInfo.CompanyOwnerStudyNo
Report date	Report date or publication date in full. For study reports this must be after the date the study was notified in the notification of studies database	Date	LITERATURE.GeneralInfo.ReportDate
Remarks	Explanatory remarks can be provided	Text area	LITERATURE.GeneralInfo.Remarks
Attached documents	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication. For published studies the article must be uploaded in PDF format if full intellectual property rights have not been obtained and the article can	Attachments list	LITERATURE.GeneralInfo.AttachedDocuments

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	<p>be used for scientific assessment purposes only. The uploaded attachment will not be included in published dossier</p>		
Attached (sanitised) documents for publication	<p>For study reports a sanitised version of the full study report must be uploaded in this field in PDF format.</p> <p>For published studies the article must be uploaded in PDF format if full intellectual property rights have been obtained. If full intellectual property rights have not been obtained, a citation including the abstract should be uploaded in this field.</p> <p>The uploaded attachment will be included in the published dossier</p>	Attachments list	LITERATURE.GeneralInfo.AttachedSanitisedDocsForPublication
Other study identifier(s)	Applies to study reports		LITERATURE.GeneralInfo.StudyIdentifiers
Study ID	Study ID should be used to report the identifier from the Notification of Studies database (NoS_Id).	Text	LITERATURE.GeneralInfo.StudyIdentifiers.StudyID
Remarks	<p>If the Notification of studies identifier is reported in 'Study ID' enter 'NoS_Id'. If the study was not notified provide a justification to explain why the study is included in the dossier to meet the data requirements but was not included in the Notification of Studies database. Example 'Study commissioned before 27 March 2021'.</p> <p>This section should be used to include justifications for study belated notifications.</p>	Text	LITERATURE.GeneralInfo.StudyIdentifiers.Remarks
Other study identifier(s)			

Links to support material

Links to support materials

<https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation>

Practical arrangement for Notification of studies

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Additional considerations

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed above. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain IPRs for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/ citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.

Test material

Purpose

For the product: A detailed description of the composition used shall be provided.

Chemicals: The test material used should be essentially the same, for the purposes of toxicological, ecotoxicological, environmental and residue testing and assessment. In the case of studies in which dosing extends over a period (for example repeated dose studies), dosing shall be done using a single batch of active substance if stability permits. When tests shall be conducted using purified active substance the purity must be (≥ 980 g/kg) of stated specification otherwise a justification shall be provided in cases where the degree of purity achieved is less than 980 g/kg.

In case of renewals, if the new (proposed) representative formulation for the renewal is different to the former (reference) formulation, it should be demonstrated by the applicant that differences are minor for the different sections (ecotox, tox...) in case that data from the former (reference) formulation should also be used for the assessment of the new (proposed) formulation.

Test material must clearly identify the batches used as test material in the different studies included in the dossier. To facilitate the assessment of the compliance of the batches used in the (eco)toxicological studies with the technical specification (Template 1.1)

Microorganisms: Where studies are conducted using micro-organisms produced in the laboratory or in a pilot plant production system, the studies must be repeated using micro-organisms as manufactured, unless it can be demonstrated that the test material used is essentially the same for the purposes of the testing and assessment

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Name	Instructions	Type	Field Path
Name	Number of the batch	Multi-line text	TEST_MATERIAL_INFORMATION.Name
Composition		Header 1	TEST_MATERIAL_INFORMATION.Composition
Composition			TEST_MATERIAL_INFORMATION.Composition.CompositionList
Type	Indicate for each component if it is a constituent, impurity or additive	Closed list	TEST_MATERIAL_INFORMATION.Composition.CompositionList.Type
Reference substance	Link to the reference substance for the component	Entity reference field	TEST_MATERIAL_INFORMATION.Composition.CompositionList.ReferenceSubstance
Concentration	Concentration of the component. For the chemical active substance and impurities this should be in g/kg.	Range with open list (Decimal)	TEST_MATERIAL_INFORMATION.Composition.CompositionList.Concentration
Remarks	Specific remarks related to the concentration of the component reported	Multi-line text	TEST_MATERIAL_INFORMATION.Composition.CompositionList.Remarks
Composition			
Composition / purity: other information	'analytical grade' or 'technical grade' can be used to provide a qualitative indication of the purity for active substances where quantification is not technically possible	Open list with remarks	TEST_MATERIAL_INFORMATION.Composition.CompositionPurityOtherInformation
Other characteristics		Header 2	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics
Test material form	Select the form of the test material	Open list with remarks (2000)	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.TestMaterialForm
Details on test material	Provide the expiry date. Differences between non-radio labelled and radio labelled can be indicated in this field.	Text template	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.DetailsOnTestMaterial
Confidential details on test material	The percent difference in concentration from the reference	Text template	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.Co

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	specification can be indicated for the active substance and impurities		nfidentialDetailsOnTest Material
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Links to support materials

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_guidance_equivalence-chem-substances_en.pdf

Template 1.1– Template for presentation the assessment for the equivalence of batches
(<https://doi.org/10.5281/zenodo.4557366>)

Endpoint summaries – common blocks

Summary naming – best practices

The name of the endpoint summary should describe the endpoint addressed, the default text can be used. One summary is normally expected for each section, if more than one endpoint summary is completed the suffix should clearly differentiate between the documents.

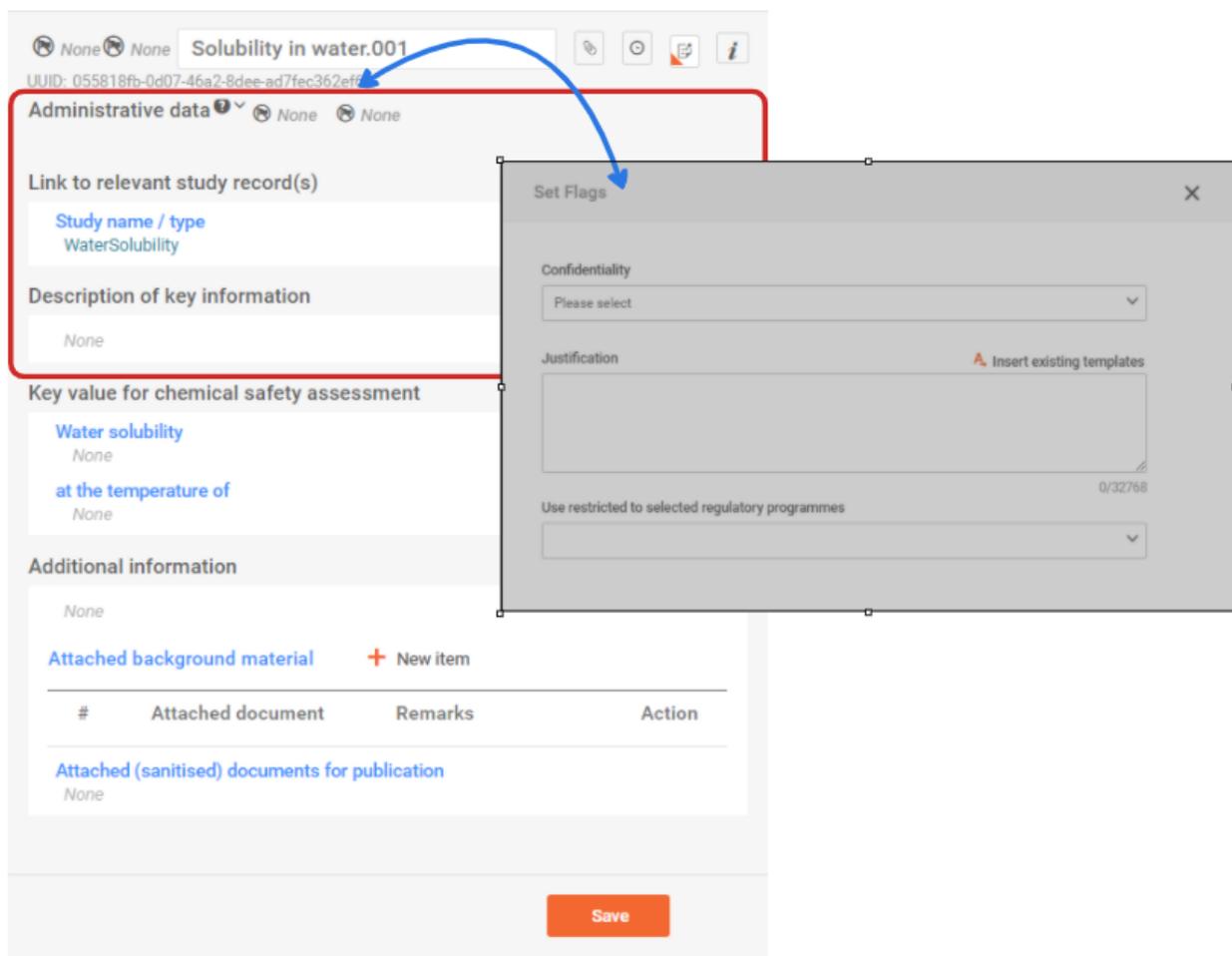
Administrative data summary – common block

Name	Instructions	Type	Field Path
Administrative data		Header 1	AdministrativeDataSummary
	<p>Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants</p> <p>Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set.</p>	Confidentiality	AdministrativeDataSummary.DataProtection
Link to relevant study record(s)	Provide here the link to the most relevant study(ies) from which the key value for safety	Header 1	LinkToRelevantStudyRecord

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	assessment is extrapolated.		
Study name / type		Endpoint reference list	LinkToRelevantStudyRecord.Link
Results		Read-only	LinkToRelevantStudyRecord.Results
Description of key information	<p>Report Information to support the most relevant endpoint. Ensure that information presented includes the information specified in the Template to be used for the List of Endpoints. Multiple endpoint summaries can be created where different DegT50 values are defined at different pH values. The pH should be specified in the 'Description of key information field</p>	Header 1	KeyInformation
		Rich text area	KeyInformation.KeyInformation

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Endpoint summary block for relevant study record

Name	Instructions	Field path
Link to relevant study records		LinkToRelevantStudyRecords
Study name / type	The study giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study	LinkToRelevantStudyRecords.StudyNameType

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	is GLP. Available epidemiological data are preferred provided that they are reliable and relevant.	
Results		LinkToRelevantStudyRecords.Results

Administrative data  None  None

Description of key information

None

Key value for chemical safety assessment

Skin irritation / corrosion

Link to relevant study records

Study name / type

 Select

press Esc to close

Endpoint conclusion

Endpoint conclusion

None

Endpoint conclusion block

Name	Instructions	Field path
Endpoint conclusion		EndpointConclusion
Endpoint conclusion		EndpointConclusion.EndpointConclusion

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Administrative data  None  None

Description of key information

None

Key value for chemical safety assessment

Skin irritation / corrosion

Link to relevant study records

Study name / type  

+ Select press Esc to close

Endpoint conclusion

Endpoint conclusion

None

Endpoint conclusion block (quality of database)

Name	Instructions	Type	Field Path
Endpoint conclusion		Header 3	EndpointConclusion
Endpoint conclusion	Adverse effect observed" should be chosen if mortality or severe effects were observed in any of the studies. "No adverse effect observed" should be chosen if no animals died or no severe effects were observed at limit dose level. If "No study available" is chosen, a justification needs to be provided.	Closed list	EndpointConclusion.EndpointConclusion
Dose descriptor	Type of reference value reported e.g. LD50. Reference value derived from the	Closed list	EndpointConclusion.EffectLevelUnit

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	reported endpoint study records		
Value		Range with closed list (Decimal)	EndpointConclusion.EffectLevelValue
Quality of whole database	The following factors should be considered: - To what extent the whole available information meets the data requirements under EU Pesticide legislation. - Reliability and consistency across different studies (i.e. quality of testing methods, size and statistical power of study design, biological plausibility, dose-response relationships and statistical testing)	Multi-line text	EndpointConclusion.DatabaseQuality

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Administrative data None None

Description of key information
None

Key value for chemical safety assessment

Acute toxicity: via oral route
Link to relevant study records
[Study name / type](#)
None

[Endpoint conclusion](#)
None

[Dose descriptor](#)
None

[Value](#)
None

[Quality of whole database](#)
None

Endpoint conclusion block (Species version)

Name	Instructions	Type	Field Path
Endpoint conclusion		Header 3	EndpointConclusion
Endpoint conclusion	Add the relevant endpoint conclusions by picking from provided list. In case where no picklist is provided, please add the relevant species / organ / system which was investigated in the study.	Closed list	EndpointConclusion.EndpointConclusion
Dose descriptor	If it is a corrected value, please indicate why.	Closed list	EndpointConclusion.EffectLevelUnit
		Unit measure with Closed List (Decimal)	EndpointConclusion.EffectLevelValue

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Study duration		Closed list	EndpointConclusion.TestType
Experimental exposure time per week (hours/week)	In this field, you should add the experimental exposure conditions in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.	Decimal	EndpointConclusion.ExperimentalExposureTimePerWeek
Species		Open list	EndpointConclusion.Species
Quality of whole database	The following factors should be considered: - To what extent the whole available information meets the data requirements under EU Pesticide legislation. - Reliability and consistency across different studies (i.e. quality of testing methods, size and statistical power of study design, biological plausibility, dose-response relationships and statistical testing)	Multi-line text	EndpointConclusion.DatabaseQuality
System		Open list	EndpointConclusion.System
Organ		Multi select open list	EndpointConclusion.Organ

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Endpoint conclusion

Endpoint conclusion

None

Dose descriptor

None

None

Study duration

None

Experimental exposure time per week (hours/week)

None

Species

None

Quality of whole database

None

System

None

Organ

None

Discussion (Header 1) – common block

Name	Instructions	Type	Field Path
Additional information	Provide additional information related to the endpoint, for example: <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any 	Header 1	Discussion

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	<p>user-derived values for the sake of transparency</p> <p>-the possible reasons for differentiating results when several studies were identified to be relevant for the assessment.</p> <p>If there is no additional information to be reported this field may be left empty.</p>		
	Provide any additional information related to the endpoint.	Rich text area	Discussion.Discussion
Attached background material	Provide the original version of any document that contains confidential material		Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the non-confidential file uploaded under "Attached (sanitised) documents for publication". If a file is uploaded under this field a confidentiality claim must be submitted for each part of the file considered confidential.	Single file attachment	Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A non-confidential version of any submitted background	Attachments list	Discussion.AttachedSanitisedDocsForPublication

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	<p>material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.</p>		
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Additional information

None

[Attached background material](#) + [New item](#)

#	Attached document	Remarks	Action
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[Attached \(sanitised\) documents for publication](#)

None

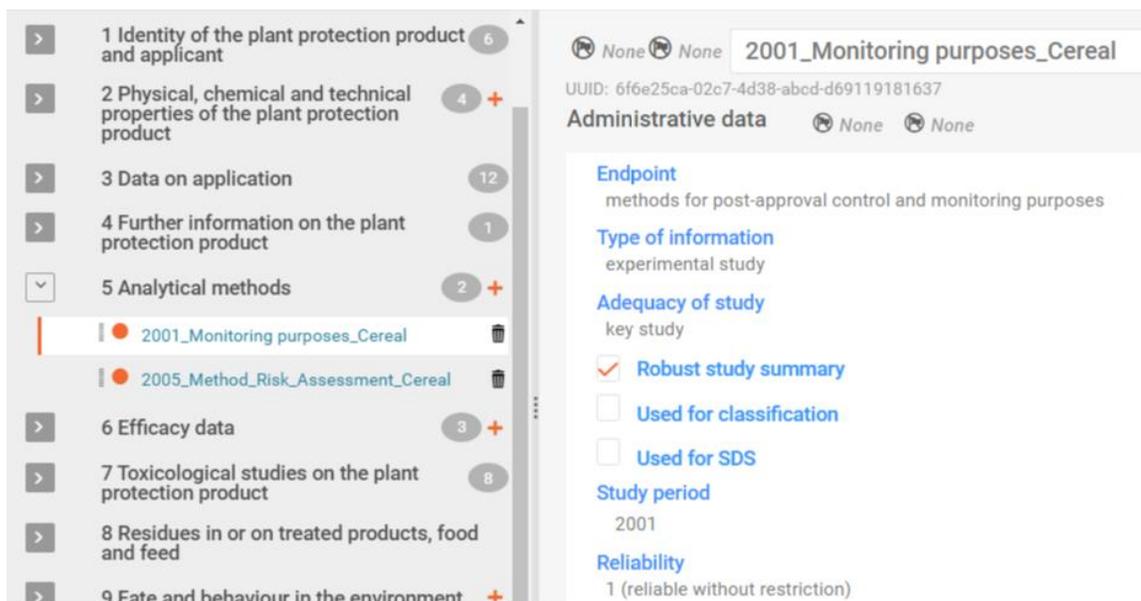
Endpoint study records – common blocks

Study naming – best practices

- 'Endpoint study records should not include author names'
- 'It is recommended to use the Year of the study, the endpoint and additional relevant context where a multiple studies exist for an endpoint.'

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- Examples:
- Analytical methods: 2007_Post-approval control and monitoring purposes_cereal
- Metabolism in plants: 2009_primary_crop_metabolism_wheat
- Feeding studies: 2010_residues in livestock_lactating_cows
- Biodegradation in soil: 2011_biodegradation in soil simulation_anaerobic
- Toxicity aquatic invertebrates: 2012_short term toxicity_daphnia magna
- Good agricultural practices (GAP).001: Crop_zone.001, ex. Apples_NEU.001



The screenshot shows the IUCLID application interface. On the left is a sidebar with navigation items: 1 Identity of the plant protection product and applicant (6), 2 Physical, chemical and technical properties of the plant protection product (4), 3 Data on application (12), 4 Further information on the plant protection product (1), 5 Analytical methods (2), 6 Efficacy data (3), 7 Toxicological studies on the plant protection product (8), 8 Residues in or on treated products, food and feed, and 9 Fate and behaviour in the environment. The '5 Analytical methods' section is expanded, showing two entries: '2001_Monitoring purposes_Cereal' and '2005_Method_Risk_Assessment_Cereal'. The main panel displays the details for '2001_Monitoring purposes_Cereal' with a UUID of 6f6e25ca-02c7-4d38-abcd-d69119181637. It includes an 'Administrative data' section with fields for Endpoint (methods for post-approval control and monitoring purposes), Type of information (experimental study), Adequacy of study (key study), Robust study summary (checked), Used for classification (unchecked), Used for SDS (unchecked), Study period (2001), and Reliability (1 (reliable without restriction)).

Administrative data – common block

Purpose

Describes how to fill in all the administrative data available on a particular endpoint study, entered into the pertinent fields. This information relate to the type of information, adequacy of study, study period, reliability, data waiving.

Name	Instructions	Type	Field Path
Administrative data		Header 1	AdministrativeData
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	See Confidentiality of dossiers	AdministrativeData.Dat aProtection

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	Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set.		
Endpoint	Select from the picklist the relevant endpoint.	Closed list with remarks	AdministrativeData.Endpoint
Type of information	Indicate 'experimental study' or 'read-across from similar mixture/product' or 'read-across from supporting substance (structural analogue or surrogate)' or 'read-across based on grouping of substances (category approach)' unless the information is retrieved from a literature search in this case indicate 'other': 'Study from literature search'	Open list with remarks	AdministrativeData.StudyResultType
Adequacy of study	Indicate the purpose of the record selecting the adequacy in terms of usefulness for fulfilling the information requirements for the hazard/risk assessment. <ul style="list-style-type: none"> A key study is a study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and 	Closed list	AdministrativeData.PurposeFlag

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	<p>representativeness of data.</p> <ul style="list-style-type: none"> • A supporting study provides some additional information to support the conclusions from the key study/ies or the weight of evidence approach. • A weight of evidence is selected to indicate that an endpoint study record contributes to a weight of evidence approach. • Disregarded due to major methodological deficiencies is a study that is available to the applicant but is not taken into account because of lack of reliability or because the study is obsolete. • Other information is other available information which does not directly contribute to the conclusions for the setting the endpoint <p>For each data requirement at least one 'key study' or two records identified as 'weight of evidence' is</p>		
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	<p>expected unless data waiving has been indicated.</p> <p>Where 'key study' or 'weight of evidence' is selected, the Validation assistant checks for document completeness.</p>		
Robust study summary	<p>Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'. If not relevant, disregard this field. 'Robust Study Summary' or in combination with 'Adequacy of study'. If not relevant, disregard this field.</p>	Check box	AdministrativeData.RobustStudy
Used for classification	<p>Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'. If not relevant, disregard this field. Not relevant for micro-organisms since they do not fall under the CLP Regulation.</p>	Check box	AdministrativeData.UsedForClassification
Used for SDS	Not relevant for EU-PPP	Check box	AdministrativeData.UsedForMSDS
Study period	Indicate the period during which the study	Text	AdministrativeData.StudyPeriod

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	<p>was conducted, i.e. start and end date.</p> <p>For 'Notified' studies this should be after the date of notification</p>		
Reliability	<p>The term reliability defines the inherent quality of a test report or publication.</p> <p>In field Reliability, enter a reliability score as judged at your discretion, i.e. 1 (reliable without restriction), 2 (reliable with restrictions), 3 (not reliable) or 4 (not assignable).</p> <p>The "other:" option may be selected if this scoring system is not used.</p> <p>Studies indicated as key study must have a reliability score of 1 or 2.</p> <p>The validation check will verify consistency between 'Adequacy of study' field and 'Reliability' field (EU_PPP_007, EU_PPP_003).</p> <p>Further explanations on the reliability assessment can be provided in the 'Rationale for reliability incl. deficiencies' field.</p>	Open list	AdministrativeData.Reliability

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	<p>For further details on reliability please consult the EFSA guidance.</p> <p>In terms of 'Acceptability / Reliability' Key studies and weight of evidence studies are considered to have 'Acceptability / Reliability' = Yes. A supporting study is considered to be 'Supportive only' The others are considered to have 'Acceptability / Reliability' = No.</p>		
<p>Rationale for reliability incl. deficiencies</p>	<p>Describe the rationale for the reliability score chosen considering the possible impact of deficiencies and/or implications on test results.</p> <p>The deviations from the guideline should be described in 'Test guideline' section but the impact of these deviations should be considered in the rationale for reliability.</p> <p>When assessing an older study against the current guideline, the current guideline can be specified in this field</p> <p>Standard justifications from picklist may be sufficient in some cases. Otherwise select</p>	<p>Open list with remarks (32000)</p>	<p>AdministrativeData.RationalReliability</p>

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	'Other' and provide for additional explanation in the 'Remarks' field.		
Data waiving	<p>If no 'key study' or 'weight of evidence' study is provided for a data requirement then data waiving must be completed. The validation check will flag when this field must be completed (EU_PPP_013).</p> <p>Select the reason for data waiving or other and provide a justification in 'Justification for data waiving' field.</p>	Closed list	AdministrativeData.Dat aWaiving
Justification for data waiving	<p>In addition to the more generic justification selected in the preceding field 'Data waiving', it is possible to provide here a more detailed justification.</p> <p>To this end one of the specific standard phrase(s) can be selected if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving'.</p> <p>Otherwise select 'other:' and enter free text.</p> <p>Validation check will flag uncomplete compiling (EU_PPP_002).</p>	Multi select open list with remarks (32000)	AdministrativeData.Dat aWaivingJustification

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Justification for type of information	This field can be used for entering free text. Please complete field only when submitting a waiving justification	Text template	AdministrativeData.JustificationForTypeOfInformation
Attached justification	A document can be uploaded to support data waiving, but it is recommended to complete in full the data waiving fields		AdministrativeData.AttachedJustification
Attached justification		Single file attachment	AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference	<p>In case the study has been reported for another data requirement use cross reference to link to the study to this section.</p> <p>The creation of duplicate versions of endpoint studies should be avoided.</p> <p>Cross reference should be used to link to an 'Analytical Methods' document when a specific method is used in a study. This allows an overview of methods used in different studies e.g. toxicology and ecotoxicology</p>		AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	AdministrativeData.CrossReference.ReasonPurpose

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Related information		Endpoint reference field	AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	AdministrativeData.CrossReference.Remarks
Cross-reference			

Links to support materials:

Appendix to: EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092. 49 pp. doi:10.2903/j.efsa.2011.2092

<https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2011.2092&file=efs22092-sup-0001-Appendix.pdf>

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Administrative data None None

Endpoint
None

Type of information
None

Adequacy of study
None

Robust study summary

Used for classification

Used for SDS

Study period
None

Reliability
None

Rationale for reliability incl. deficiencies
None

Data waiving
None

Justification for data waiving
None

Justification for type of information
None

Attached justification + New item

#	Attached justification	Reason / purpose	Action
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Cross-reference + New item

#	Reason / purpose for cross-...	Related information	Remarks	Action
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Data source (Literature Reference) – common block

Name	Instructions	Type	Field Path
Data source		Header 1	DataSource
Reference	Link to Literature reference In cases where an addendum has been issued and it is not part full study report pdf, a literature reference for the addendum should be created with Reference type = other:addendum.	Literature reference list	DataSource.Reference

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	This literature reference should also be included in the Data source Reference.		
Data access	<p>Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use.</p> <p>Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer.</p>	Open list with remarks	DataSource.DataAccess
Data protection claimed	<p>Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates).</p> <p>In the supplementary remarks field, include an</p>	Closed list with remarks	DataSource.DataProtectionClaimed

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	<p>explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for justification see attached document X')</p>		
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Additional considerations:

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed above. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain IPRs for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/ citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.

Reference	None
Data access	None
Data protection claimed	None

Figure 2.2: Data source block

Material and methods – common block

Name	Instructions	Type	Field Path
Test guideline	Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used		Guideline

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	<p>is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.</p> <p>Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline).</p>		
Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - 'according to guideline' (if a given test guideline was followed); - 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline'); - 'no guideline available' (if so, fill in field 'Principles of method if other than guideline'); - 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'); 	Closed list	Guideline.Qualifier
Guideline	<p>Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the</p>	Open list	Guideline.Guideline

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	<p>related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.</p> <p>If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.</p> <p>Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'.</p>		
<p>Version / remarks</p>	<p>In this text field, you can enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline); - To indicate if the 	<p>Multi-line text</p>	<p>Guideline.VersionRemarks</p>

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	<p>study was performed prior to the adoption of the test guideline specified;</p> <ul style="list-style-type: none"> - To indicate if the methodology used was based on an extension of the test guideline specified; - To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. 		
Deviations	<p>In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>	Closed list with remarks	Guideline.Deviation
Test guideline			
Principles of method if other than guideline	<p>If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for</p>	Text template	MethodNoGuideline

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	<p>'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.</p> <p>For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed.</p> <p>Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available.</p> <p>Also provide a justification for using this method if appropriate.</p>		
GLP compliance	<p>Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes' is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed.</p>	Closed list with remarks	GLPComplianceStatement
Other quality assurance	<p>Indicate any non-GLP quality assurance system adhered to, if any.</p>	Open list with remarks	OtherQualityAssurance

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Type of method	Indicate which type of method was used according to the options provided in the test guideline or, if no guideline was applied, according to the methodology used.	Closed list with remarks	MethodType
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Links to support material:

[GEP https://www.eppo.int/ACTIVITIES/plant_protection_products/gep](https://www.eppo.int/ACTIVITIES/plant_protection_products/gep)

Materials and methods

Test guideline + New item

#	Qualifier	Guideline	Version / remarks	Deviations	Action
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Principles of method if other than guideline

None

GLP compliance

None

Test material – common block

Name	Instructions	Field path
Test material	All TM batches should be entered in the TM entity manager and then the appropriate TM selected	TestMaterials
Test material information	Select the appropriate Test material If more than one test batch is used in a study single representative batch can be used	TestMaterials.TestMaterialInformation
Specific details on test material used for the study	Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can	TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy

	<p>include information on the pre-defined items, but not all or additional ones may be relevant. The determination shall also include quantities of unknown materials, if any, to account for 100% of the sample</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof.</p> <p>If applicable, relevant available information on the following items should be given:</p> <p>RADIOLABELLING INFORMATION</p> <ul style="list-style-type: none"> - Radiochemical purity - Specific activity - Locations of the label - Expiration date of radiochemical substance <p>STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL</p> <ul style="list-style-type: none"> - Storage condition of test material - Stability under test conditions - Solubility and stability of the test substance in the solvent/vehicle - Reactivity of the test substance with the solvent/vehicle or the cell culture medium <p>TREATMENT OF TEST MATERIAL PRIOR TO TESTING</p>	
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	<ul style="list-style-type: none"> - Treatment of test material prior to testing (e.g. warming, grinding) - Preliminary purification step - Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle) <p>FORM AS APPLIED IN THE TEST (if different from that of starting material)</p> <p>Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.</p> <p>FORMULATED PRODUCT (for biocides/pesticides)</p> <p>Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment.</p> <p>OTHER SPECIFICS</p> <p>Provide any other relevant information needed for characterising the tested material.</p>	
<p>Specific details on test material used for the study (confidential)</p>	<p>Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-</p>	<p>TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential</p>

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	<p>defined items, but not all or additional ones may be relevant. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof.</p> <p>If applicable, relevant available information on the following items should be given:</p> <p>RADIOLABELLING INFORMATION</p> <ul style="list-style-type: none"> - Radiochemical purity - Specific activity - Locations of the label - Expiration date of radiochemical substance <p>STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL</p> <ul style="list-style-type: none"> - Storage condition of test material - Stability under test conditions - Solubility and stability of the test substance in the solvent/vehicle - Reactivity of the test substance with the solvent/vehicle or the cell culture medium <p>TREATMENT OF TEST MATERIAL PRIOR TO TESTING</p> <ul style="list-style-type: none"> - Treatment of test material prior to testing (e.g. warming, grinding) - Preliminary purification step - Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or 	
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	<p>dissolved solid) to final concentration and the solvent(s) used</p> <p>- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)</p> <p>FORM AS APPLIED IN THE TEST (if different from that of starting material)</p> <p>Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.</p> <p>FORMULATED PRODUCT (for biocides/pesticides)</p> <p>Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment.</p> <p>OTHER SPECIFICS</p> <p>Provide any other relevant information needed for characterising the tested material.</p>	
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Materials and methods

Test guideline + New item

#	Qualifier	Guideline	Version / remarks	Deviations	Action
Principles of method if other than guideline <i>None</i>					
GLP compliance <i>None</i>					
Test material					
Test material information <i>None</i>					
Specific details on test material used for the study <i>None</i>					
Specific details on test material used for the study (confidential) <i>None</i>					

Test animals (OHT: Repeated dose toxicity)

Name	Instructions	Field path
Test animals		TestAnimals
Species	Select species as appropriate. If not available from picklist, select 'other' and specify.	TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.	TestAnimals.Strain
Details on species / strain selection	For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of species and strain.	TestAnimals.DetailsOnSpeciesStrainSelection
Sex	Select as appropriate. If females were used, indicate in field "Details on test animals and environmental conditions" whether nulliparous and non-pregnant.	TestAnimals.Sex
Details on test animals or test system and environmental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - Food quality and water quality: provide analytical information on the nutrient and dietary contaminant levels. Similarly provide analytical information on the drinking water used in the study.	TestAnimals.OrganismDetails

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	- IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing).	
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<p>Test animals</p> <p>Species None</p> <p>Strain None</p> <p>Details on species / strain selection None</p> <p>Sex None</p> <p>Details on test animals or test system and environmental conditions None</p>
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Results of examinations BLOCK (OHT: Repeated dose toxicity: oral)

Name	Instructions	Data type	IUCLID6 Path
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservClinSigns
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other	Text area	DescriptionIncidenceAndSeverityObservClinSigns

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	<p>information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Dermal irritation (if dermal study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservDermalIrritationIfDermalStudy
Description (incidence and severity)		Text area	DescriptionIncidenceAndSeverityObservDermalIrritationIfDermalStudy
Dermal irritation		Closed list	ObservDermalIrritation
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results</p>	Text area	DescriptionIncidenceAndSeverityObservDermalIrritation

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	incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list	ObservMortality
Description (incidence)	Describe the incidence of mortality by sex and dose group. An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.	Text area	DescriptionIncidenceMortality
Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservBodyweight
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	DescriptionIncidenceAndSeverityObservBodyweight

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	<p>adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservFoodConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.	Text area	DescriptionIncidenceAndSeverityObservFoodConsum

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	<p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Food efficiency	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservFoodEfficiency
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results</p>	Text area	DescriptionIncidenceAndSeverityObservFoodEfficiency

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	<p>incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Water consumption and compound intake (if drinking water study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservWaterConsum
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological</p>	Text area	DescriptionIncidenceAndSeverityObservWaterConsum

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	<p>significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Ophthalmological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservOphthalm
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on</p>	Text area	DescriptionIncidenceAndSeverityObservOphthalm

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	the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservHaematol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservHaematol

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Clinical biochemistry findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservClinChem
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservClinChem
Endocrine findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	EndocrineFindings

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	examined' or 'not specified' as applicable.		
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	DescriptionIncidenceAndSeverityEndocrine
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservUrin
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations	Text area	DescriptionIncidenceAndSeverityObservUrin

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	<p>were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Behaviour (functional findings)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservNeurobehaviour
Description (incidence and severity)	<p>Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards).</p> <p>Describe the incidence and severity of effects by sex and dose group.</p>	Text area	DescriptionIncidenceAndSeverityObservNeurobehaviour

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	<p>At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Immunological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ImmunologicalFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the</p>	Text area	DescriptionIncidenceAndSeverityImmunological Findings

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	<p>effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Organ weight findings including organ / body weight ratios	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservOrganWeights
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or</p>	Text area	DescriptionIncidenceAndSeverityObservOrganWeights

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	<p>irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Gross pathological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservGrpathol
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other</p>	Text area	DescriptionIncidenceAndSeverityObservGrpathol

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	<p>information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Neuropathological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservNeuropathol
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the</p>	Text area	DescriptionIncidenceAndSeverityObservNeuropathol

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	<p>toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Histopathological findings: non-neoplastic	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservHistopathol
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p>	Text area	DescriptionIncidenceAndSeverityObservHistopathol

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	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Histopathological findings: neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservHistopatholNeoplastic
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s)	Text area	DescriptionIncidenceAndSeverityObservHistopatholNeoplastic

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	(predefined table) may be mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityOtherEffects
Details on results	Provide any other relevant details if not entered in the specific	Text area	DetailsOnResults

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	"Description" fields for the examined parameters.		
<div style="border: 1px solid #ccc; padding: 10px;"> <p>Results and discussion</p> <p>Results of examinations</p> <p>Clinical signs <i>None</i></p> <p>Description (incidence and severity) <i>None</i></p> <p>Mortality <i>None</i></p> <p>Description (incidence) <i>None</i></p> <p>Body weight and weight changes <i>None</i></p> <p>Description (incidence and severity) <i>None</i></p> <p>Food consumption and compound intake (if feeding study) <i>None</i></p> <p>Description (incidence and severity) <i>None</i></p> <p>Food efficiency <i>None</i></p> <p>Description (incidence and severity) <i>None</i></p> <p>Water consumption and compound intake (if drinking water study) <i>None</i></p> <p>Description (incidence and severity) <i>None</i></p> <p>Ophthalmological findings <i>None</i></p> <p>Description (incidence and severity)</p> </div>			

Effect levels BLOCK (OHT 67-69, 72-74)

Name	Instructions	Data type	Field path
			Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific	Check box	Efflevel.KeyResult

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	guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.		
Dose descriptor	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Closed list with remarks	Efflevel.Endpoint
Generation		Closed list	Efflevel.Generation
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it	Open list with remarks	Efflevel.BasedOn

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	is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.		
Sex	Select from drop-down list.	Closed list	Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select closed list with remarks (32000)	Efflevel.Basis
Remarks on result	This field can be used for: <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' 	Open list with remarks (2000)	Efflevel.RemarksOnResults

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Effect levels

+ New item

#	Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result	Action
1	<input type="checkbox"/> Key result	None	None	None	None	None	None	

Target system BLOCK (OHT RepDoseTox etc.)

Name	Instructions	Data type	Field path
	Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.		TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	TargetSystemOrganToxicity.CriticalEffectsObserved

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Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Closed List (Decimal)	TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Closed list	TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	TargetSystemOrganToxicity.RelevantForHumans

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Target system / organ toxicity

[+ New item](#)

#	Key result	Critical effects o...	Lowest effective...	System	Organ	Treatment related	Dose response r...	Relevant for hu...	Action
1	<input type="checkbox"/> Key result	None	None	None	None	None	None	None	

Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)

Name	Instructions	Field path
Sampling and analysis		SamplingAndAnalysis
Analytical monitoring	Indicate whether test substance was monitored in the test solutions or suspensions. The remarks field can be used to reference the analytical methods endpoint study record for the method used	SamplingAndAnalysis.AnalyticalMonitoring
Details on sampling	If the concentration of test material was monitored, enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate.	SamplingAndAnalysis.DetailsOnSampling
Details on analytical methods	If the concentration of test material was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) for the different matrices as appropriate.	SamplingAndAnalysis.DetailsOnAnalyticalMethods
Test solutions		TestSolutions
Vehicle	Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility. If yes, specify in field 'Details on test solution'.	TestSolutions.Vehicle
Details on test solutions	Use freetext template and delete/add elements as appropriate. Enter any details	TestSolutions.DetailsOnTestSolutions

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	<p>that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>If a solvent control is included, detail whether a dilution water (procedural) control was also included or omitted.</p>	
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Materials and methods

[Test guideline](#) + New item

#	Qualifier	Guideline	Version / remarks	Deviations	Action
Principles of method if other than guideline					
		None			
GLP compliance					
		None			
Test material					
Test material information					
		None			
Specific details on test material used for the study					
		None			
Specific details on test material used for the study (confidential)					
		None			
Sampling and analysis					
Analytical monitoring					
		None			
Details on sampling					
		None			
Details on analytical methods					
		None			
Test solutions					
Vehicle					
		None			
Details on test solutions					
		None			

Sampling_Test substrate BLOCK (OHT: Terrestrial tox.)

Name	Instructions	Field path
Sampling and analysis		SamplingAndAnalysis
Analytical monitoring	Indicate whether test substance was monitored in the test solutions	SamplingAndAnalysis.AnalyticalMonitoring

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	<p>or suspensions. For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.</p>	
Details on sampling	<p>If the amount of test material exposed to the organisms was monitored, enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate. Note: Indicate which concentrations were measured if not all. As applicable, provide information for soil, stock and/or spray solution.</p>	SamplingAndAnalysis.DetailsOnSampling
Details on analytical methods	<p>If the amount of test material exposed to the organisms was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate.</p>	SamplingAndAnalysis.DetailsOnAnalyticalMethods
Test substrate		TestSubstrate
Vehicle	<p>Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility. If yes, specify in field 'Details on preparation and application of test substrate'.</p>	TestSubstrate.Vehicle
Details on preparation and application of test substrate	<p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	TestSubstrate.DetailsOnPreparationAndApplicationOfTestSubstrate

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Materials and methods

[Test guideline](#) + New item

#	Qualifier	Guideline	Version / remarks	Deviations	Action
Principles of method if other than guideline					
		None			
GLP compliance					
		None			
Test material					
Test material information					
		None			
Specific details on test material used for the study					
		None			
Specific details on test material used for the study (confidential)					
		None			
Sampling and analysis					
Analytical monitoring					
		None			
Details on sampling					
		None			
Details on analytical methods					
		None			
Test substrate					
Vehicle					
		None			
Details on preparation and application of test substrate					
		None			

Study design BLOCK (OHT: Aquatic tox.)

Name	Instructions	Field path
Study design		StudyDesign
Test type	Select appropriate test type.	StudyDesign.TestType
Water media type	Indicate whether organisms were tested in fresh-/salt- or brackish/estuarine or other water.	StudyDesign.WaterMediaType
Limit test	Indicate if the experiment was a limit test.	StudyDesign.LimitTest
Total exposure duration	Enter numeric value & unit.	StudyDesign.TotalExposureDuration
Remarks on exposure duration	Enter any remarks related to the total exposure duration.	StudyDesign.RemarksOnExposureDuration

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Post exposure observation period	Indicate the post-observation period if appropriate.	StudyDesign.PostExposureObservationPeriod
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Study design

Test type
None

Water media type
None

Limit test
None

Total exposure duration
None

Remarks on exposure duration
None

Post exposure observation period
None

Study design BLOCK (OHT: Terrestrial tox.)

Name	Instructions	Field path
Study design		StudyDesign
Test type	Select appropriate test type.	StudyDesign.TestType
Study type	Indicate the study type, i.e. laboratory study, extended laboratory study (e.g. with a more natural substrate), aged-residue study, semi-field study (mimicking a near-natural environment with ambient climatic conditions) or field study (using natural populations).	StudyDesign.StudyType
Substrate type	Select type of substrate.	StudyDesign.SubstrateType
Limit test	Indicate if the experiment was a limit test.	StudyDesign.LimitTest
Total exposure duration	Enter numeric value.	StudyDesign.TotalExposureDuration
Remarks	Enter any remarks related to the total exposure duration.	StudyDesign.Remarks
Post exposure observation period	Indicate the post-observation period (with unit) if appropriate, e.g. in the case of a reproduction test.	StudyDesign.PostExposureObservationPeriod

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Study design

Test type
None

Study type
None

Substrate type
None

Limit test
None

Total exposure duration
None

Remarks
None

Post exposure observation period
None

Test conditions block

Name	Instructions	Field path
Test conditions		TestConditions
Hardness	Indicate water hardness as mg/L calcium carbonate equivalent values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	TestConditions.Hardness
Test temperature	Indicate test temperature values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. As appropriate state the location (e.g. water bath, test chambers) and type of measurement (e.g. continuous monitoring). Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	TestConditions.TestTemperature
pH	Indicate pH values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Indicate how mean pH is to be	TestConditions.Ph

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	obtained. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	
Dissolved oxygen	Indicate dissolved oxygen values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	TestConditions.DissolvedOxygen
TOC		TestConditions.TOC
Salinity	For marine studies, indicate salinity (if relevant) values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	TestConditions.Salinity
Ammonia		TestConditions.Ammonia
Conductivity	Indicate conductivity values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field.	TestConditions.Conductivity

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Test conditions
None

Hardness
None

Test temperature
None

pH
None

Dissolved oxygen
None

Salinity
None

Conductivity
None

Nominal and measured concentrations
None

Details on test conditions
None

Reference substance (positive control)
None

Any other information on materials and methods incl. tables
None

Test conditions BLOCK (OHT: Terrestrial tox.)

Name	Instructions	Field path
Test conditions		TestConditions
Test temperature		TestConditions.TestTemperature
pH		TestConditions.Ph
pH (if soil or dung study)		TestConditions.PhIfSoilStudy
Moisture		TestConditions.Moisture
Humidity		TestConditions.Humidity
Photoperiod and lighting		TestConditions.PhotoperiodAndLighting
Organic carbon content (% dry weight)		TestConditions.OrganicCarbonContent
Nitrogen content (% dry weight)		TestConditions.NitrogenContent
Details on test conditions		TestConditions.DetailsOnTestConditions

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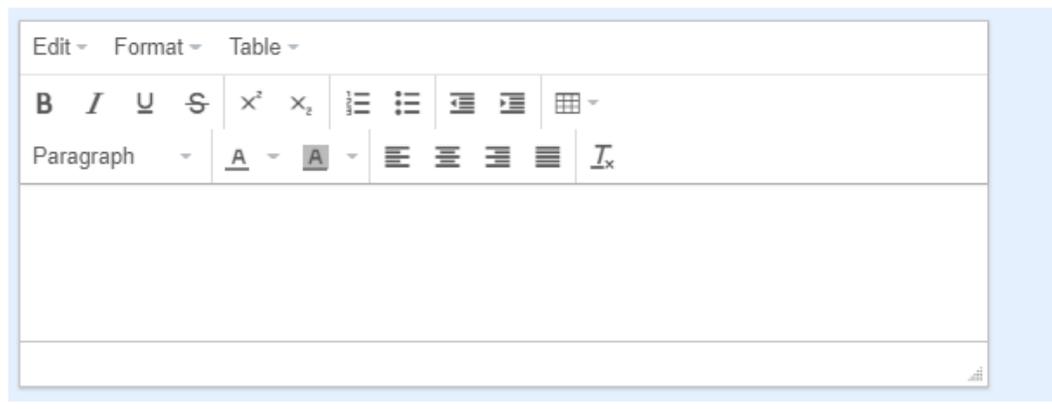
Test conditions
Test temperature None
pH None
Moisture None
Details on test conditions None

Any other information on materials and methods incl. tables - (H2) – common block

Name	Instructions	Field Path
Any other information on materials and methods incl. tables		AnyOtherInformationOnMaterialsAndMethodsInclTables
	<p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation

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Any other information on materials and methods incl. tables



Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)

Name	Instructions	Field path
Effect concentrations	Report the relevant effect levels (e.g. EC50, LC50 and/or other). Repeat this block of fields for entering more than one effect level if necessary.	EffectConcentrations
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	EffectConcentrations.KeyResult
Species	Select from drop-down list.	EffectConcentrations.Species
Duration	Enter numeric value and unit.	EffectConcentrations.Duration
Dose descriptor	Indicate the derived dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects. If it is a corrected value, please indicate why.	EffectConcentrations.Endpoint
Effect conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	EffectConcentrations.EffectConc
Nominal / measured	Indicate whether the effect concentration is based on nominal, measured (initial / geometric mean / arithmetic mean), measured (time weighted average = TWA), measured (not specified), acid	EffectConcentrations.NominalMeasured

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	equivalent or estimated. Select 'not specified' if not known.	
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	EffectConcentrations.ConcBasedOn
Basis for effect	Select effect parameter such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	EffectConcentrations.BasisForEffect
Basis for effect	Select effect parameters such as inhibition of respiratory rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	EffectConcentrations.BasisForEffect Multi
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' Note: Where a test was done, but no value could be achieved based on the method and boundaries used it is recommended to report the upper or lower value with relevant qualifier, e.g. EC50 >10 mg/L (if this was the highest concentration tested). An additional explanation	EffectConcentrations.RemarksOnResults

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	should be given in this field, e.g. 'not determinable because of methodological limitations' plus free text, e.g. 'highest concentration tested'.	
Effect concentrations		
Details on results	<p>Briefly summarise relevant observations and any dose response relationship. Information on toxicity, infectiveness and pathogenicity must be reported.</p> <p>Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if anyavailable, and tailor it/them to your needs or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). As appropriate also attach a figure with growth curves in field 'Attached background material'. Note: Specific tables may be required.</p>	ResultsDetails
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.</p>	ResultsRefSubstance
Reported statistics and error estimates	<p>Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.</p>	Statistics

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Results and discussion

Effect concentrations [+ New item](#)

#	Key result	Species	Duration	Dose descri...	Effect conc.	Nominal / m...	Conc. based...	Basis for eff...	Remarks on...	Action
Details on results										
None										
Results with reference substance (positive control)										
None										
Reported statistics and error estimates										
None										

Transformation products BLOCK (OHT)

Name	Instructions	Field path
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.	IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	IdentityTransformation.ReferenceSubstance
Identity of transformation products		

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Results and discussion

For thermal stability study
[Test substance thermally stable](#)
None

[Operating temperature](#) + New item

#	Key result	Operating temp.	Remarks on result	Action
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[Sublimation](#)
None

[Transformation products](#)
None

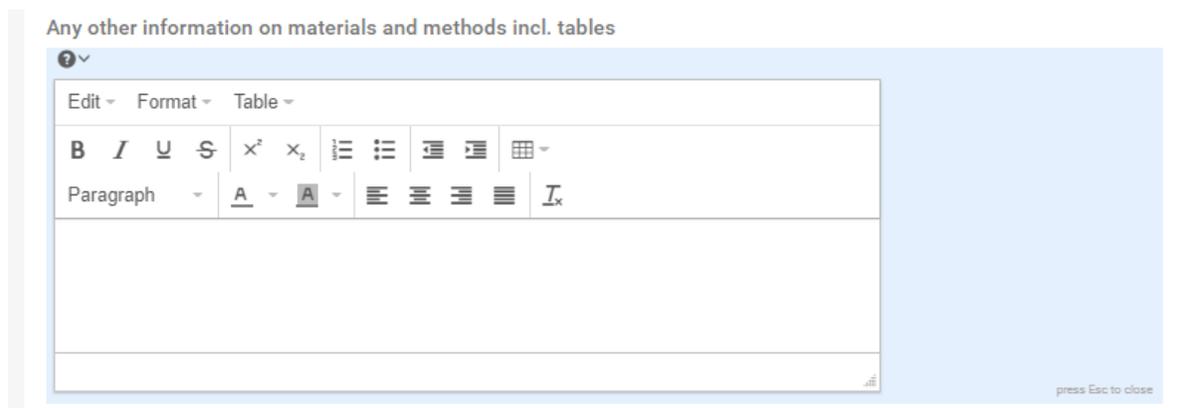
[Identity of transformation products](#) + New item

#	No.	Reference substance	Action
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Any other information on results incl. tables Block

Name	Instructions	Field path
Any other information on results incl. tables		AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	AnyOtherInformationOnResultsInclTables.OtherInformation

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Overall remarks, attachments – common block

Name	Instructions	Type	Field Path
Overall remarks, attachments		Header 1	OverallRemarksAttachments
Overall remarks	<p>In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	Rich text area	OverallRemarksAttachments.RemarksOnResults

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Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.		OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document	<p>Provide any additional documents relevant for the submission, not already provided under the methods or results section or in the full study report. See IUCLID templates for PPP Risk Assessment Templates on EFSA Knowledge Junction (zenodo).</p> <p>For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section.</p> <p>Note that the original file only needs to be attached here, if it differs from the file in Attached (sanitised) documents for publication. and can be uploaded here if not yet done in the results section.</p>	Single file attachment	OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached	Text	OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks

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	document if the file name is not self-explanatory.		
Attached background material			
Attached full study report	The full study report should be uploaded in the Literature Reference for the study. However additional background material can be attached here. The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Attachments list	OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)	Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document.	Image	OverallRemarksAttachments.IllustrationPictureGraph
Attached (sanitised) documents for publication	The full study report should be uploaded in the Literature Reference for the study. However additional background material can be attached here. Check individual endpoint study records for information on subject specific attachments e.g. PRIMO model.	Attachments list	OverallRemarksAttachments.AttachedSanitisedDocsForPublication

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Overall remarks, attachments

Overall remarks
None

Attached background material + New item

#	Attached document	Remarks	Action
Attached full study report None			
Illustration (picture/graph) None			
Attached (sanitised) documents for publication None			

Applicants summary and conclusion – common block

Name	Instructions	Type	Field Path
Applicant's summary and conclusion		Header 1	ApplicantSummaryAndConclusion
Validity criteria fulfilled	<p>State whether validity criteria in the test guideline have been fulfilled or not. Use supplementary remarks field to state the criteria and supporting information.</p> <p>Clearly indicate if the criteria used are not consistent with those given by the test guideline. If so, give justification in field 'Rationale for reliability incl. deficiencies' as to why this study summary is considered reliable.</p>	Closed list with remarks	ApplicantSummaryAndConclusion.ValidityCriteriaFulfilled
Interpretation of results	Conclude if the study results fall under relevant classification criteria of the Globally Harmonised System of Classification and Labelling of Chemicals	Closed list with remarks (2000)	ApplicantSummaryAndConclusion.InterpretationOfResults

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	<p>(UN GHS). Further explanations can be entered in the supplementary remarks field.</p> <p>Note that a classification in the strict sense cannot always be based on an individual study, but includes a weight of evidence evaluation of all relevant data. To this end wording such as 'is classified in Category 1' should be used only in the conclusions provided in the relevant classification section.</p>		
Conclusions	<p>This field should be used to summarise the conclusions by the applicant and will be used in study summaries produced using report generator.</p>	Text area	ApplicantSummaryAndConclusion.Conclusions
Executive summary	<p>If relevant for the respective regulatory programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document.</p>	Rich text area	ApplicantSummaryAndConclusion.ExecutiveSummary

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Applicant's summary and conclusion

Interpretation of results
None

Conclusions
None

Executive summary
None

Validation rules

Summary	Issue Type	Message	Target documents	Checked field reference
QLT_PPP_001: Endpoint must be indicated	Quality rules/Warning	'Administrative data' is not complete. The 'Endpoint' addressed by the study record must be indicated.	All endpoint study records	Administrative data – common block
QLT_PPP_002: Data waiving must be justified	Quality rules/Warning	'Administrative data' is not complete. If you want to submit a data waiving then the rationale for waiving the information requirement must be indicated in the field 'Data waiving' and an appropriate justification must be selected in the field 'Justification for data waiving'. If none of the available	All endpoint study records	Administrative data – common block

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		<p>justifications in the picklist apply, select 'other:' and provide the justification in the below field.</p> <p>If you wish to provide further information in support of the data waiving, use the field 'Justification for type of information' and/or attach a document under 'Attached justification' heading. A reference to a record with relevant information for the data waiving can be made under 'Cross-reference' heading.</p>		
QLT_PPP_003: Reliability must be provided for KS and WoE	Quality rules/Warning	'Administrative data' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Reliability' must be provided. Note: If you select 'other:' then the below field must be filled in.	All endpoint study records	Administrative data – common block

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<p>QLT_PPP_004: Reference must be provided for KS and WoE</p>	<p>Quality rules/Warning</p>	<p>'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' the 'Reference' entry must be completed. For each reference, the 'Year' or the 'Report date' must always be indicated. In addition, as a minimum, the following must be provided:</p> <p><Display dynamic message depending on selection in 'Reference type' field></p> <p>#study report# - If the data is from a study report, the field 'Testing facility' (with the full address of the testing laboratory, including city and country) and either 'Report no.', 'Study no.' or 'Title' must be provided.</p> <p>#other company data# - If the data is from a company,</p>	<p>All endpoint study records</p>	<p>Data source (Literature Reference) – common block</p>
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		<p>either the field 'Report no.' or the field 'Study no.' must be provided. In addition, information must be given under 'Author', 'Study sponsor' and/or 'Title'.</p> <p># publication, review article or handbook, secondary source or grey literature# - If the data is from a literature source, the field 'Bibliographic source' must be provided. Sufficient information should be given to be able to identify the literature source.</p> <p>#other: or no selection# <Merge and display all the above></p>		
QLT_PPP_005: Guideline must be given for KS, WoE and testing proposal	Quality rules/Warning	'Materials and methods' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, the test guideline (to be) used in the	All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms	Material and methods – common block

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		<p>study must be indicated in the 'Guideline' under the 'Test guideline' heading. If you add several entries, then the 'Guideline' must be specified for each of them. If the test guideline applied is not found in the picklist, select 'other:' and provide information on the guideline in the below field.</p> <p>If no test guideline can be specified (e.g. because the study is a non-guideline study, or (Q)SAR was applied), a description of the principles of the test protocol or the method must be provided in the field 'Principles of method if other than guideline'.</p>		
QLT_PPP_006: Test material must be given for KS, WoE and testing proposal	Quality rules/Warning	'Materials and methods' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal,	All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms	Test material – common block

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		<p>the test material (to be) used in the study must be identified by linking a test material information (TMI) record in the 'Test material information' entry.</p> <p>The TMI record should contain sufficient information to allow the understanding of the identity of the tested substance. As a minimum, under 'Composition' at least one 'Constituent' must be reported. Each created component must contain at least one of the following identifiers in the designated fields: EC number, CAS number, IUPAC name.</p> <p>For a read-across target record, the test material information should identify the target substance of the read-across.</p>		
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<p>QLT_PPP_007: Key studies should have reliability 1 or 2</p>	<p>Quality rules/Warning</p>	<p>Administrative data is inconsistent. This endpoint study record has been indicated with the adequacy 'key study' but the assigned 'Reliability' score indicates that the study is not reliable. A key study is expected to correspond to a robust study summary of sufficient quality and reliability (score 1 or 2) to independently fulfil the information requirements for an endpoint. You are advised to reconsider whether this study is of sufficient quality to be used as key study to fulfil the information requirements for this endpoint.</p>	<p>All endpoint study records</p>	<p>Administrative data – common block</p>
<p>QLT_PPP_008: Deviations in the guideline must be explained</p>	<p>Quality rules/Warning</p>	<p>Materials and methods is inconsistent. In the entry 'Test guideline' the field 'Deviations' has been set to 'yes'. In this case, you are expected to provide a brief explanation</p>	<p>All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms</p>	<p>Material and methods – common block</p>

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		<p>summarising the deviations from the guideline in the below 'Remarks' field. More detailed information should be described in the respective fields of the 'Materials and methods' part. Moreover, all possible effects that such a deviation may have on the obtained test results should be analysed and reported in the 'Overall remarks, attachments' part of the endpoint study record.</p>		
<p>QLT_PPP_009: Attached (sanitised) documents for publication must be provided for KS/WoE (all ESR)</p>	<p>Quality rules/Warning</p>	<p>'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' the entry 'Reference' must be completed. For each reference a version of the full study report must be provided under the 'Attached (sanitised) documents for publication' field. - If the information is confidential, a</p>	<p>All endpoint study records</p>	<p>Literature reference</p>

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		sanitised version should be provided under the 'Attached (sanitised) documents for publication' and the confidential report should be added under the 'Attached documents' field in the Literature reference.		
QLT_PPP_010: Study ID and/or Justification (remarks) must be provided	Technical completeness check	'Data source', '<Reference table name>', Other studies identifiers is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Study ID' under Data source, Reference must be filled in, or a justification for not providing a Study ID must be provided under 'Remarks' field. - If the study has been notified in the Notification of Studies Database then report the number in the 'Study ID' field of the Literature Reference for the study. The type of identifier should be NoS_ID. If the study has not	All endpoint study records	Literature reference

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		been notified provide a justification in the 'Remarks' field in the Literature reference.		
QLT_PPP_011: KS/WoE must be provided for all required sections (Substance_MO)	Quality/Warning	Section <x.x>: At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section. Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement.	All endpoint study records	Administrative data – common block
QLT_PPP_012: Summaries must be provided for all required sections (Substance_MO)	Quality rules/Warning	Section <x.x>: At least one endpoint study summary must be provided for this section.	ENDPOINT_SUMM ARY.Effectiveness AgainstTargetOrg anisms ENDPOINT_SUMM ARY.ToxicityToOth erAboveGroundOr ganisms ENDPOINT_SUMM ARY.AnalyticalMet hods ENDPOINT_SUMM ARY.ExposureRela tedObservationsH umans ENDPOINT_SUMM ARY.Sensitisation ENDPOINT_SUMM ARY.AcuteToxicity	N/A

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			<p>ENDPOINT_SUMMARY.SpecificInvestigationsOtherStudies</p> <p>ENDPOINT_SUMMARY.GeneticToxicity</p> <p>ENDPOINT_SUMMARY.RepeatedDoseToxicity</p> <p>ENDPOINT_SUMMARY.AdditionalToxicologicalInformation</p> <p>ENDPOINT_SUMMARY.MigrationOfResiduesIntoAndTheirBehaviourOnFoodOrFeedingstuffs</p> <p>ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs</p> <p>ENDPOINT_SUMMARY.MagnitudeResiduesPlants</p> <p>ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities</p> <p>ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs</p> <p>ENDPOINT_SUMMARY.EnvironmentalFateAndPathways</p> <p>ENDPOINT_SUMMARY.AdditionalInformationOnEnvironmentalFateAndBehaviour</p> <p>ENDPOINT_SUMMARY.BiodegradationInSoil</p>	
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			<p>ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests</p> <p>ENDPOINT_SUMMARY.PhototransformationInAir</p> <p>ENDPOINT_SUMMARY.OtherDistributionData</p> <p>ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP</p> <p>ENDPOINT_SUMMARY.AquaticToxicity</p> <p>ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP</p> <p>ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP</p> <p>ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP</p> <p>ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP</p> <p>ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP</p> <p>ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP</p> <p>ENDPOINT_SUMMARY.ToxicityMicroorganisms</p> <p>ENDPOINT_SUMMARY.ToxicityTerre</p>	
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			<p> strialArthropods_EU_PPP ENDPOINT_SUMMARY.ToxicitySoilMicroorganisms_EU_PPP ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP ENDPOINT_SUMMARY.AdditionalEcotoxicologicalInformation ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP </p>	
QLT_PPP_013	Quality/Warning	<p>Section <x.x>: At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section. Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement.</p> <ul style="list-style-type: none"> - To indicate an endpoint study record as a key study or as part of a weight of evidence approach, select 	All endpoint study records	

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		<p>'key study' or 'weight of evidence' in the 'Adequacy of study' picklist and fill in all relevant fields under 'Administrative data', 'Data source', 'Materials and methods', and 'Results and discussion' for this endpoint.</p> <p>Other types of study summaries (e.g. supporting studies) should be filled in as much as possible.</p> <ul style="list-style-type: none"> - To indicate an endpoint study record as data waiving, make a selection in the field 'Data waiving' and provide a justification in the field 'Justification for data waiving'. 		
QLT_PPP_014	Quality/Warning	Section <x.x>: At least one endpoint study summary must be provided for this section.	All endpoint summaries	
QLT_PPP_017	Quality/Warning	Section <x.x>: At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section.	All endpoint study records	

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		<p>Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement.</p> <ul style="list-style-type: none"> - To indicate an endpoint study record as a key study or as part of a weight of evidence approach, select 'key study' or 'weight of evidence' in the 'Adequacy of study' picklist and fill in all relevant fields under 'Administrative data', 'Data source', 'Materials and methods', and 'Results and discussion' for this endpoint. <p>Other types of study summaries (e.g. supporting studies) should be filled in as much as possible.</p> <ul style="list-style-type: none"> - To indicate an endpoint study record as data waiving, make a selection in the field 'Data waiving' and provide a 		
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		justification in the field 'Justification for data waiving'.		
QLT_PPP_018	Quality/Warning	Section <x.x>: At least one endpoint study summary must be provided for this section.		
QLT_PPP_019	Quality/Warning	Section <x.x>: At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section. Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement. - To indicate an endpoint study record as a key study or as part of a weight of evidence approach, select 'key study' or 'weight of evidence' in the 'Adequacy of study' picklist and fill in all relevant fields under 'Administrative data', 'Data		

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		<p>source', 'Materials and methods', and 'Results and discussion' for this endpoint. Other types of study summaries (e.g. supporting studies) should be filled in as much as possible. - To indicate an endpoint study record as data waiving, make a selection in the field 'Data waiving' and provide a justification in the field 'Justification for data waiving'.</p>		
<p>QLT_PPP_020: Summaries must be provided for all required sections (Substance_MRL)</p>	<p>Quality rules/Warning</p>	<p>Section <x.x>: At least one endpoint study summary must be provided for this section. #Indicate the section number in the message. A separate message is displayed for each section.#</p>		
<p>QLT_PPP_021: At least one Mixture Composition must exist with linked Active (Substance)_PP P_All_Submissions</p>	<p>Quality rules/Warning</p>	<p>Mixture composition is incomplete. At least one Mixture composition must be present in the dossier function. This must include a linked substance which has the the Function = 'active substance'.</p>	<p>FLEXIBLE_RECORD.MixtureComposition</p>	<p>N/A</p>

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<p>QLT_PPP_022: At least one valid constituent must exist (for each Active substance) All_EU_PPP</p>	<p>Quality rules/Warning</p>	<p>For each Active substance composition, at least one constituent must be defined. All constituents must be identified by linking a reference substance.</p>	<p>FLEXIBLE_RECORD.MixtureComposition FLEXIBLE_RECORD.SubstanceComposition</p>	<p>N/A</p>
<p>QLT_PPP_023: At least one LE composition must exist in Active substance dataset_Only Active sub.</p>	<p>Quality rules/Warning</p>	<p>Each substance must be identified by at least one specification of purity. Specify the following information: - Degree of purity of the active substance - Constituents - Impurities, if applicable - Additives, if applicable</p> <p>Each constituent, impurity and additive must be identified by linking a reference substance, complete with available identifiers and molecular and structural information, and by providing the concentration range.</p>	<p>FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition</p>	<p>N/A</p>
<p>QLT_PPP_024: each (active) substance must have a reference</p>	<p>Quality rules/Warning</p>	<p>A reference substance must be linked in IUCLID section 1.1.</p>	<p>1.1_Identification FLEXIBLE_RECORD.MixtureComposition</p>	<p>N/A</p>

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<p>substance in section 1,1 All_EU_PPP</p>			SUBSTANCE	
<p>QLT_PPP_025: All Active substances must be the same (same UUID)_ All_PPP</p>	<p>Quality rules/Warning</p>	<p>Mixture compositions is incomplete. Where more than one mixture (product formulation/preparation) is reported, the components with the Function = 'active substance' must be the same. This is confirmed by checking that the substance UUID for each active substance is identical.</p>	<p>1.1_Identification FLEXIBLE_RECORD.MixtureComposition SUBSTANCE</p>	<p>N/A</p>
<p>QLT_PPP_026: at least one GAP must be created in All_PPP</p>	<p>Quality rules</p>	<p>Section 2, Good Agricultural Practices (GAP) is incomplete. At least one Good Agricultural Practices (GAP) must be created. The following fields must be complete: - Crop / treated object, - Target organisms: at least one row must be created with at least 'Scientific name' or 'Common name' fields being filled in) - Method of</p>	<p>FLEXIBLE_RECORD.GAP</p>	<p>N/A</p>

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		<p>application</p> <ul style="list-style-type: none"> - Growth stage is mandatory if GAP refers to a crop; if GAP refers to treatment of non-crop objects (children of 3NOCF0) or to children codes of 3CRPA0 (treatment of crop parts) it is not required; if GAP refers to treatment of harvested crops (children codes of 3HARVO), BBCH 99 should be provided. If number of applications is greater than 1, the information on the growth stage needs to be reported for the first and the last application. Treatment season is not mandatory. - Number of applications (range) - Application rate per treatment (product) – range - Application rate per treatment for target a.s. (range) - Pre-harvest interval (either the days of PHI or 'not applicable'). 		
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<p>QLT_PPP_027: Exactly one literature reference must be provided in KS, WoE ESRs_All_EU_PP</p>	<p>Quality rules</p>	<p>'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' exactly one 'Reference' entry must be provided. The entry must be complete, the 'Year' or the 'Report date' must always be indicated. In addition, as a minimum, the following must be provided:</p> <ul style="list-style-type: none"> - If the data is from a study report, the field 'Testing facility' (with the full address of the testing laboratory, including city and country) and either 'Report no.', 'Study no.' or 'Title' must be provided. - If the data is from a company, either the field 'Report no.' or the field 'Study no.' must be provided. In addition, information must be given under 'Author', 'Study sponsor' and/or 'Title'. - If the data is 	<p>All endpoint study records</p>	<p>Literature reference</p>
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		<p>from a literature source, the field 'Bibliographic source' must be provided. Sufficient information should be given to be able to identify the literature source.</p>		
<p>QLT_PPP_028: All reference substances in sections 1.1 and 1.2 of Active substance must contain an identifier_Active Sub & MRL</p>	<p>Quality rules/Warning</p>	<p>Reference substance information is not complete. Each reference substance must contain at least one of the following identifiers in the designated fields: EC number, CAS number, IUPAC name. If you use a reference substance to report (a group of) unknown constituents/impurities, you need to enter in the IUPAC name field: "Unknown constituents/impurities". In addition you should specify, as far as possible, the number and nature of these unknown constituents/impurities in the 'Remarks' field of the</p>	<p>1.1_ Identification, 1.2_ Composition, FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition, SUBSTANCE</p>	<p>Reference substance v.6.4 (Final)</p>

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		constituent/impurity block.		
QLT_PPP_029: All constituents in the first composition record in Active substance must represent distinct substance identities_All_PPP	Quality rules/Warning	Multiple constituents in the active substance composition/purity specification are identified with the same reference substance. Remove the duplicate entries.	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition	N/A
QLT_PPP_030: Constituents should have a typical concentration_Active Sub & MRL	Quality rules/Warning	The 'Typical concentration' for each Active substance composition constituent should be specified (value and unit). The value should be representative for the substance as manufactured/imported. Active substance composition results shall include quantitative data, in terms of g/kg content, for all components present in quantities of 1 g/kg or more.	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition	N/A
BR_PPP_033	Business rule/Failure	Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.	DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES	N/A

