IUCLID Microbial Active Substances Manual

European Food Safety Authority (EFSA)

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Introduction

REGULATORY BACKGROUND FOR MICROBIAL PESTICIDE ACTIVE SUBSTANCES APPLICATIONS

The **procedures** for approval and renewal of approval of microbial 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 844/2012[4] – 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 844/2012[4].

DATA REQUIREMENTS FOR MICROBIAL PESTICIDE ACTIVE SUBSTANCES APPLICATIONS

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

[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

plant protection products on the market, and in the **Commission Regulation (EU) No 544/2011**[6] ("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) 2019/1381[2]), 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**[7].

These new requirements, as implemented by the **Practical Arrangements**[8] 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**[9]**"** and apply to all **pesticides applications submitted as of 27 March 2021**.

The **IUCLID dossier for a microbial pesticide 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) (for secondary metabolites/toxins provide data as available);
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 Microorganisms - active substance application (product)**'.

With regards to the GUIDANCE ON THE RISK ASSESSMENT OF METABOLITES PRODUCED BY MICROORGANISMS USED AS PLANT PROTECTION ACTIVE SUBSTANCES [10] the step of 'Collecting a basic set of information on metabolites' can be reported in the Biological properties of the microorganism document in section 4 of the active substance dataset.

For reporting **secondary metabolites/toxins**, the following approach should be followed:

1. If the secondary metabolite/toxin is produced by the active substance during the manufacturing of the product (and is **part of the product**), it should be added as a **component** of the **product mixture composition**, under Section 1.4.

[6] 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

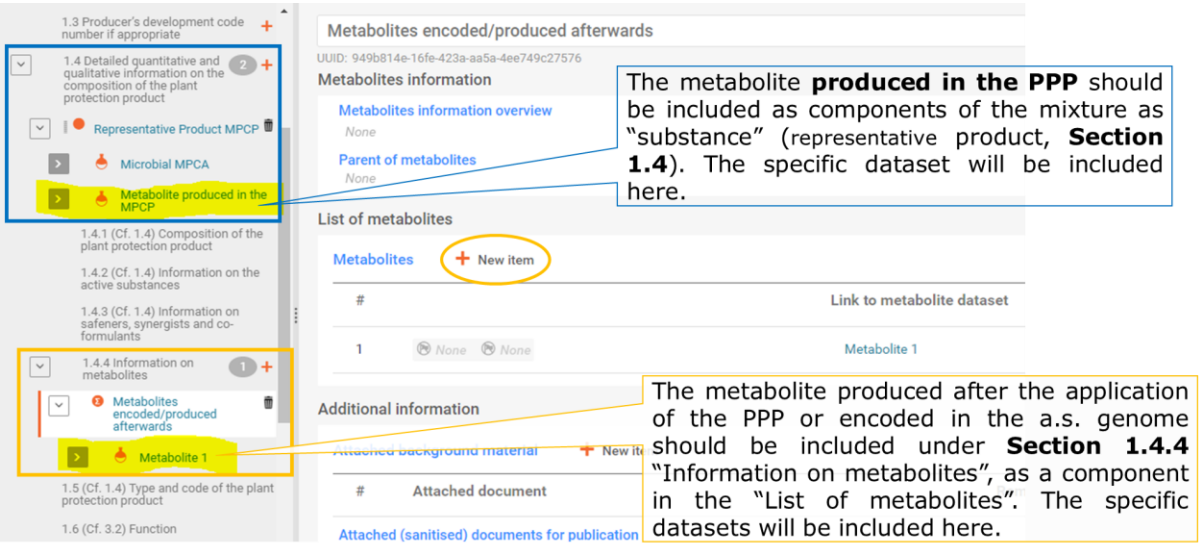
[7] Ref: Commission working document under revision

[8] https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements

[9] https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance

[10] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_180653_microorganism- metabolites-concern_202011.pdf

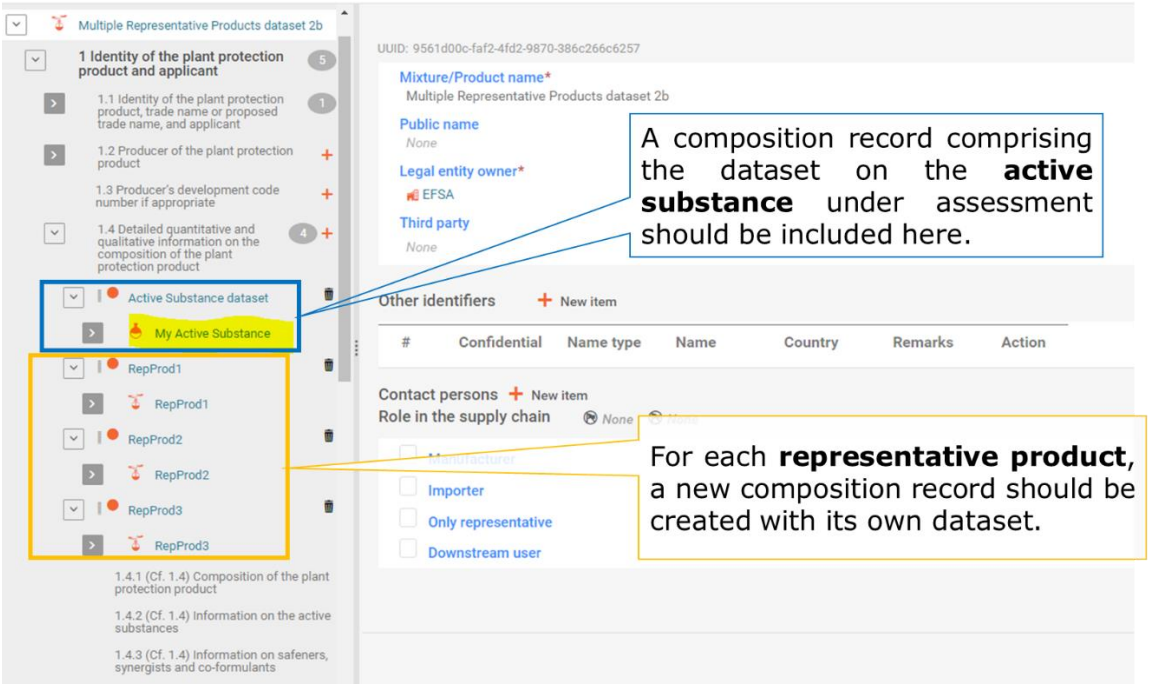
2. If the secondary metabolite/toxin is not present in the product but can be (potentially) produced by the active substance once it is released in the environment (i.e. *in situ*), it should be included under Section 1.4.1 "Information on metabolites", as a component in the "List of metabolites". This document can be used to list the metabolites of potential concern. The metabolites should be linked to other substance datasets.



The overall conclusion on the metabolites of potential concern can be provided in the summary document in section 5.6 Other basic studies and additional toxicological information.

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.



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 (SANCO/10181/2013) for microbial plant protection product (PPP) dossiers to IUCLID 6.5 has been published on EFSA knowledge junction (EFSA, 2020[11]);

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

[11] European Food Safety Authority (EFSA). (2020). Crosswalks IUCLID 6.5 EU PPP Microorganisms - active substance application (product) to KMA&KMP [Data set]. Zenodo. http://doi.org/10.5281/zenodo.4313303

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 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**
- 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 10 in the active substance dataset, Section 12 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 10.2 (active substance) and Section 12 (Product) of the present 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[12]. 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 only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008.

OUTDATED DOSSIER FILES MAPPING INTO IUCLID

The detailed crosswalks from the EU Table of Contents (SANCO/10181/2013) for microbial plant protection product (PPP) dossiers to IUCLID 6.5 has been published on EFSA knowledge junction (EFSA, 2020[11]). 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[11]**Error! 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** will be only published in Zenodo (together with Physchem and Tox as well); templates for

[12] https://www.oecd.org/ehs/templates

rest of sections will be published sequentially in Zenodo (Residues, Fate and behaviour in the Environment).
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
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

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 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;
- 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:

i. 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

ii. 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, 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"*[13]

[13] 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

and "*AttachedStudyReport*". These fields are reserved for the confidential versions of documents and/or study reports 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.[14]

A comprehensive description of applicable procedures and provisions is available in EFSA's Practical Arrangements concerning transparency and confidentiality.

"AttachedSanitisedDocsForPublication" exists. This does not mean that information regarding the description of the substance composition cannot be claimed confidential.

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

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.

EU PPP Microorganisms - active substance application (product)

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_MICROORGANISMS_FOR_MIXTURES			
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_MIXTURES.DossierSubject.DossierCreationDateTime
Dossier submission remark	The EFSA question number if allocated can	Text area	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MI

	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'		XTURES.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 selected, provide the justification for an amendment of the approval conditions for an active substance in the remarks.	Closed list with remarks (2000)	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.ActiveSubstanceApproval.ApplicationPurpose
Joint application	If the purpose of the application is 'renewal of	Closed list with remarks (2000)	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MI

	an active substance for use in plant protection products' then whether the submission is a 'Joint application' must be indicated. If 'no' is selected, then a justification must be provided in the 'remark' If 'yes' provide a UUID for the joint submission and the Legal entity name for the main dossier		XTURES.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
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_MICROORGANISMS_FOR_MIXTURES.NotificationOfStudies.PreApplicationId.PreApplicationId
Pre-application identification			
Studies requiring NoS justification			DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.NotificationOfSt

			udies.StudiesReqJustification
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_MICROORGANISMS_FOR_MIXTURES.NotificationOfStudies.StudiesReqJustification.NosId
Justification	Justification for the absence of the NoS ID in the dossier	Multi-line text	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.NotificationOfStudies.StudiesReqJustification.Justification
Studies requiring NoS justification			
Attached information		Header 2	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.NotificationOfStudies.AttachedInformation
Attachment			DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.NotificationOfStudies.AttachedInformation.Attachment
Attachment	Attached administrative documents to support the application. Documents with confidential or personal information should not be attached here (e.g. letters). Remarks are used to indicate the topic/reason for including the attachment The Summary and Evaluation document should be used for including confidential attachments in the dossier. This is recommended as these documents foresee the	Single file attachment	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES.NotificationOfStudies.AttachedInformation.Attachment.Attachment

	possibility to upload confidential and non-confidential/sanitised versions of the same attachment. Scientific information should be uploaded into documents in the Table of Contents of the dossier		
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 material:
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

The following documents are located under section 1 "Identity of the plant protection product and applicant":

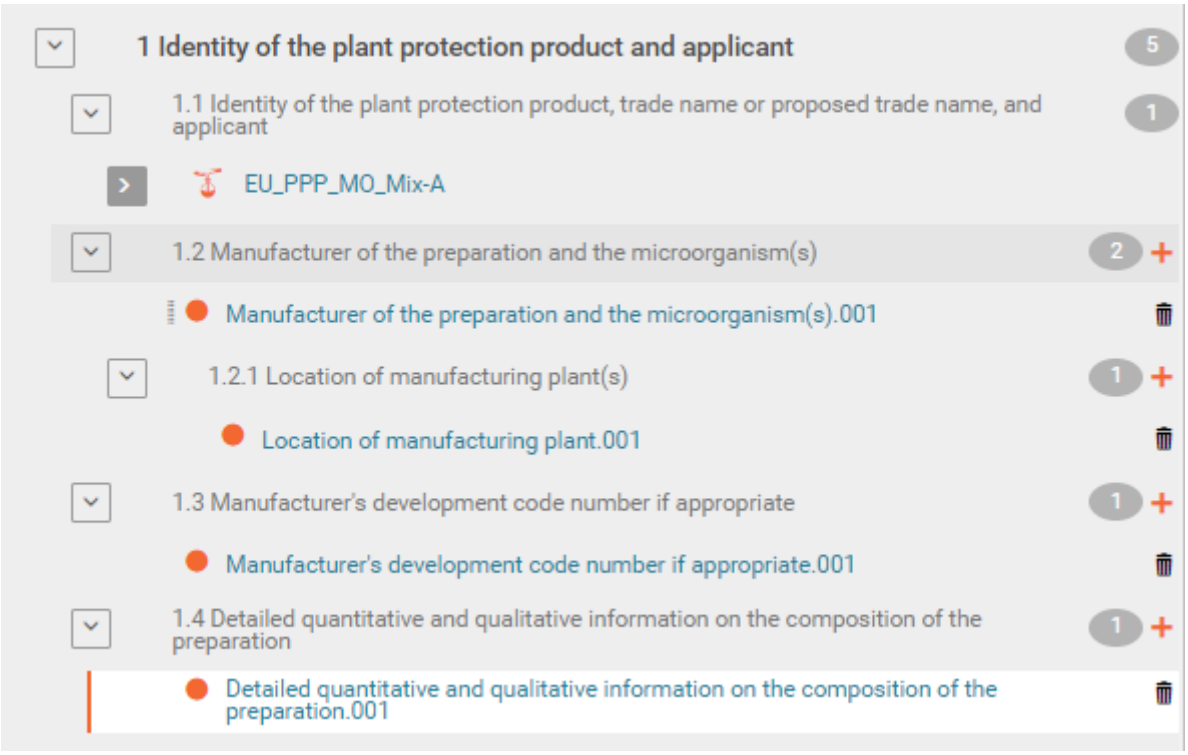
1.1 Identity of the plant protection product, trade name or proposed trade name, and applicant: Mixture entity

1.2 Manufacturer of the preparation and the microorganism(s): Suppliers – Flexible record

1.2.1 Location of manufacturing plant(s): Sites – Flexible record

1.3 Manufacturer's development code number if appropriate: Identifiers – Flexible record

1.4 Detailed quantitative and qualitative information on the composition of the preparation: Mixture Composition – Flexible record



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

Mixture			
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		MIXTURE.OtherNames

	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		
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'. 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.	Entity reference field	MIXTURE.OwnerLegalEntity
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		MIXTURE.ContactPersons

	for the dossier should be provided, name, position, telephone and e-mail address		
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
Downstream user		Check box	MIXTURE.RoleInSupplyChain.DownstreamUser

Links to support materials
Legal entity

1.2 Manufacturer of the preparation and the microorganism(s)

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			
Name	Instructions	IUCLID6 DataType	Field Path
	Set the confidentiality flag and regulatory purpose. Confidentiality of	Confidentiality	FLEXIBLE_RECORD.Suppliers.DataProtection

	dossiers submitted via IUCLID - practical instructions for applicants		
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 linked to the Substance or Mixture/Product dataset. To complete the information of this newly created Legal entity, click the Goto button The modifications will be automatically updated by clicking the Save button. The Back button will lead back to section 1.7 Suppliers. The link can be deleted by clicking the Delete button.	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 manufacturer. Click the Attachment	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.NonEUManufacturerAssignment

	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.		
Other importers	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.		FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries
Name	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. 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 Go to button. The modifications will be automatically updated by clicking the	Entity reference field	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries.LegalEntity

	Save button `. The Back button 'will lead back to section 1.7 Suppliers. The link can be deleted by clicking the Delete button.		
Agreement	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.	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.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.Suppliers			
Name	Instructions	IUCLID6 DataType	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	Entity reference field	FLEXIBLE_RECORD.Suppliers.ManufacturerImportForm.LegalEntity

	trigger the opening of the Legal entity creation dialogue. 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 The modifications will be automatically updated by clicking the Save button. The Back button will lead back to section 1.7 Suppliers. The link can be deleted by clicking the Delete button.		
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 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.	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.NonEUManufacturerAssignment
Other importers	The other Importers of the same substance, from the same non-EU manufacturer, are considered to be downstream users for		FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries

	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.		
Name	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. 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 Go to button. The modifications will be automatically updated by clicking the Save button. The Back button will lead back to section 1.7 Suppliers. The link can be deleted by clicking the Delete button.	Entity reference field	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries.LegalEntity
Agreement	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	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries.Agreement

	remarks if appropriate in the Properties window.		
Other importers			

1.3 Manufacturer'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			
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	Text area	FLEXIBLE_RECORD.Iden

	any additional comments here.		tifiers.RegulatoryProgrammeIdentifiers.RegulatoryProgrammeIdentifiers.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 preparation

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

FLEXIBLE_RECORD.MixtureComposition			
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.Components.Components
Component flag	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.MixtureComposition.Components.Components.DataProtecti

			on
Name	Link to a reference substance or substance. Select substance for the active substance/micro-organism and relevant impurities. This creates a dataset for each component of this type. Link to reference substance for other components e.g. safeners, synergists, co-formulants, by-products, culture medium etc.	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	Complete the Typical concentration reporting %w/w. For microorgansims, the nominal content of viable material is required and concentration range reporting g/kg (or g/l for liquids). For relevant impurities the range including the maximum content is required. For microorganisms the range - maximum and minimum viable material is required Where relevant, the corresponding content of the variant (such as salts and esters) of the active substances should be included as components.	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
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.Components.SubstanceGeneratedInSitu

Links to support material:
Catalogue of pesticide formulation types and international coding system

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

The following documents are located under section 2 "Physical, chemical and technical properties of the plant protection product":

2. Physical, chemical and technical properties of the plant protection product – Endpoint summary

2.1 Appearance: Appearance / physical state / colour Endpoint summary / Endpoint study record

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

2.2.1 Effects of light, temperature and humidity on technical characteristics of the product: Stability: thermal, sunlight, metals Endpoint summary / Endpoint study record

2.2.2 Other factors affecting stability: Storage stability and reactivity towards container material Endpoint summary / Endpoint study record

2.3 Explosive and oxidising properties

2.3.1 Explosive properties: Explosiveness Endpoint summary / Endpoint study record

2.3.2 Oxidising properties: Oxidising properties Endpoint summary / Endpoint study record

2.4 Flash point and other indications of flammability or spontaneous ignition

2.4.1 Flash point: Flash point Endpoint summary / Endpoint study record

2.4.2 Flammability: Flammability Endpoint summary / Endpoint study record

2.4.3 Self-heating: Auto-Flammability Endpoint summary / Endpoint study record

2.5 Acidity, alkalinity and pH value: pH Endpoint summary / Endpoint study record

2.6 Viscosity and surface tension

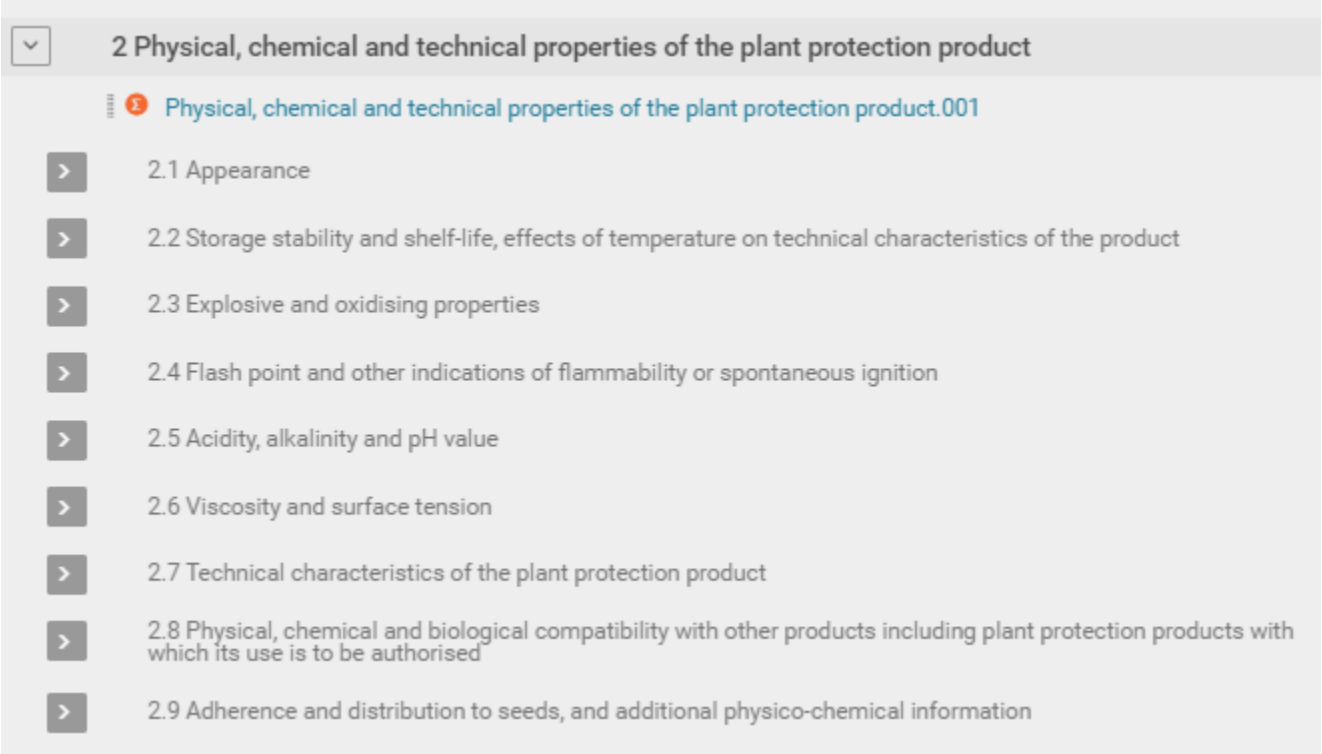
2.6.1 Viscosity: Viscosity Endpoint summary / Endpoint study record

2.6.2 Surface tension: Surface tension Endpoint summary / Endpoint study record

2.7 Technical characteristics of the plant protection product – Endpoint study record

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

2.9 Adherence and distribution to seeds, and additional physico-chemical information: Additional physico-chemical information Endpoint summary / Endpoint study record



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

ENDPOINT_SUMMARY.PhysicalChemicalProperties			
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

Appearance - 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. a description of both the colour and odour, if any, and the physical state of the preparation, must be provided.

ENDPOINT_SUMMARY.GeneralInformation			
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	Conclude on the colour and odour of the product/substance/preparation Indicate also the purity of the product/substance/preparation	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
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

Appearance - Endpoint study record

Purpose
A description of both the colour and odour, if any, and the physical state of the plant protection product shall be provided.

ENDPOINT_STUDY_RECORD.GeneralInformation			
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
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. 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. 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 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. Refer to the guidance documents of the relevant regulatory framework as to the use of this or other	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneralInformation.ResultsAndDiscussion.FormBlock.Form

	template(s) for specifying the physical state, form and other properties of the submission substance during reasonably expected use. 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.		
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

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

2.2.1 Effects of light, temperature and humidity on technical characteristics of the product

Effects of light, temperature and humidity on technical characteristics of the product - Endpoint summary

Purpose
Summary information of the effects of light, temperature, and humidity.
Effect of low temperatures on physical stability for liquid preparations

ENDPOINT_SUMMARY.StabilityThermal			
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

Effects of light, temperature and humidity on technical characteristics of the product - Endpoint study record

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.

ENDPOINT_STUDY_RECORD.StabilityThermal			
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.D

			ataSource
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_RECORD.StabilityThermal.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.StabilityThermal.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.StabilityThermal.MaterialsAndMethods.TestMaterials.TestMaterialInformation
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_RECORD.StabilityThermal.MaterialsAndMethods.StudyDesign
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_RECORD.StabilityThermal.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.StabilityThermal.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion
For thermal stability study		Header 2	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.ThermalStability

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_RECORD.StabilityThermal.ResultsAndDiscussion.ThermalStability.TestSubstanceThermallyStable
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_RECORD.StabilityThermal.ResultsAndDiscussion.ThermalStability.OperatingTemperature
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.StabilityThermal.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.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.StabilityThermal.ResultsAndDiscussion.ThermalStability.OperatingTemperature.RemarksOnResults

	by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.		
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 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.StabilityThermal.ResultsAndDiscussion.ThermalStability.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
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityThermal.ApplicantSummaryAndConclusion

2.2.2 Other factors affecting stability

Other factors affecting stability - 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			
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

Other factors affecting stability - Endpoint study record

Purpose
Effect of exposure to air, packaging, etc., on the product stability must be explored.

ENDPOINT_STUDY_RECORD.StorageStability			
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 storage stability or reactivity towards container material. Multiple selection is	Open list with remarks	ENDPOINT_STUDY_RECORD.StorageStability.MaterialsAndMethods.StudyDesign.ContainerMateri

	possible. If not listed, select 'other' and specify. Any additional information can be provided in the supplementary remarks text.		al
Details on study design	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 weigth 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 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). - OTHER: Include any other relevant information.	Text template	ENDPOINT_STUDY_RECORD.StorageStability.MaterialsAndMethods.StudyDesign.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.StorageStability.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.StorageStability.Re

			sultsAndDiscussion
Results	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'). As appropriate also attach any figures in field 'Attached background material'.	Text template	ENDPOINT_STUDY_RECORD.StorageStability.ResultsAndDiscussion.Results
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_RECORD.StorageStability.ResultsAndDiscussion.TransformationProducts
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_RECORD.StorageStability.ResultsAndDiscussion.ContainerMaterial
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.StorageStability.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.StorageStability.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.StorageStability.ApplicantSummaryAndConclusion

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

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

2.3 Explosive and oxidizing properties

2.3.1 Explosive properties

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			
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
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

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			
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
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		ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.SmallS

	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.		calePreliminaryTests
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
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		ENDPOINT_STUDY_RECORD.Explosiveness.ResultsAndDiscussion.ResultsOfTestSeriesForExplosives

	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
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

2.3.2 Oxidising properties

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			
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

Oxidising properties - Endpoint study record

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

ENDPOINT_STUDY_RECORD.OxidisingProperties			
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) (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 6;	Header 1	ENDPOINT_STUDY_RECORD.OxidisingProperties.MaterialsAndMethods

	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 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 oxygen equivalency (Ci), and the numeric results. As appropriate, enter remarks in the respective subfield and/or field		ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultOxidisingGases

	'Remarks on result'. Copy this block of fields for more than one parameter 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.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
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 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		ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingLiquids

	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.TestResultsOxidisingLiquids.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.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
Test results (Oxidising liquids)			
Test results (Oxidising solids)	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'. Copy this block of fields for more than		ENDPOINT_STUDY_RECORD.OxidisingProperties.ResultsAndDiscussion.TestResultsOxidisingSolids

	one parameter as appropriate, i.e. to record the maximum 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 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
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

2.4 Flash point and other indications of flammability or spontaneous ignition

2.4.1 Flash point

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			
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

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			
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 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	ENDPOINT_STUDY_RECORD.FlashPoint.Material

		field	sAndMethods.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 use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.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.ResultsAndDiscussion.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.ResultsAndDiscussion.FlashPoint.RemarksOnResults
Flash point			
Sustaining combustibility	If a sustaining combustibility test was conducted, specify the test procedure		ENDPOINT_STUDY_RECORD.FlashPoint.ResultsA

	used and report the test result. If necessary, copy this block of fields for test run.		ndDiscussion.Sustaining Combustibility
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.Sustaining Combustibility.KeyResult
Test procedure	Specify the test procedure used.	Open list with remarks	ENDPOINT_STUDY_RECORD.FlashPoint.ResultsAndDiscussion.Sustaining Combustibility.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.Sustaining Combustibility.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.Sustaining Combustibility.RemarksOnResults
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

2.4.2 Flammability

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			
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

Flammability - Endpoint study record

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.

ENDPOINT_STUDY_RECORD.Flammability			
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
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 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. In field 'Remarks on result' you can indicate if no flammability occurred (no flammable range with air at 20°C and		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableGasesLowerAndUpperExplosionLimit

	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.KeyResult
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 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	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 an aerosol (which means an aerosol dispenser) was tested for flammability, indicate the type of aerosol tested, the		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.Aerosols

	respective test parameter and the result. In field 'Remarks on 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.		
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.Aerosols.KeyResult
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
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.Flammability.ResultsAndDiscussion.Aerosols.RemarksOnResults

	- entering any remarks by selecting 'other:'.		
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'. If a solid was tested for flammability, report the test procedure used and the measured burning time. In field 'Remarks on result' you can indicate if no flammability occurred or if it was not determinable or measured. Copy this block of fields for specifying the relevant values.		ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.FlammableSolids
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

	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, 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; - 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 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 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. Copy this block of fields for specifying the relevant values.		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 or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.KeyResult
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	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.PyrophoricLiquids.Temp

		(Decimal)	
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 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
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; - 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.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 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. 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. 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.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases

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.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.KeyResult
Test procedure	Select the step(s) of the test procedure from the multiple drop-down list.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.TestProcedure
Max. rate of gas release	Enter a numeric value to specify the maximum rate of gas release.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Flammability.ResultsAndDiscussion.SubstancesMixturesWhichInContactWithWaterEmitFlammableGases.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

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

2.4.3 Self-heating

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			
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

Self-heating Endpoint study record

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.

ENDPOINT_STUDY_RECORD.AutoFlammability			
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 (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
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		ENDPOINT_STUDY_RECORD.AutoFlammability.ResultsAndDiscussion.AutoFlammability

	determined in the respective subfield. 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.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.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 85emark (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-	Enter a single numeric value in the	Range with	ENDPOINT_STUDY_REC

ignition temperature	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.	closed list (Decimal)	ORD.AutoFlammability.ResultsAndDiscussion.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 86emark (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 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 '>', '>=' 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.SelfIgnitionTemperatureOfDustAccumulation.SelfIgnitionTemperature
Volume / surface	Enter a numeric value to specify the	Decimal	ENDPOINT_STUDY_REC

ratio (m)	volume / surface ratio (unit: m).		ORD.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 87emark (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
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

2.5 Acidity, alkalinity and pH value

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			
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

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			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Ph.AdministrativeData
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.Ref

			erence
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.Ph.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.Ph.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.Ph.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Reagents		Header 2	ENDPOINT_STUDY_RECORD.Ph.MaterialsAndMethods.Reagents
Reagent	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.Ph.MaterialsAndMethods.Reagents.Reagent
Titration of acidity and alkalinity		Header 2	ENDPOINT_STUDY_RECORD.Ph.MaterialsAndMethods.TitrationOfAcidityAndAlkalinity
Details on titrant used	Use freetext 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	Check box	ENDPOINT_STUDY_RECORD.Ph.ResultsAndDisc

	relevance for hazard/risk assessment or classification purpose.		ussion.phValue.KeyResult
pH 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.Ph.ResultsAndDiscussion.phValue.Value
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 block of fields for different conditions.		ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.AcidityOrAlkalinity
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.AcidityOrAlkalinity.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	Closed list	ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.AcidityOrAlkalinity.AcidityOrAlkalinity

	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.		
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.Ph.ResultsAndDiscussion.AcidityOrAlkalinity.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.Ph.ResultsAndDiscussion.AcidityOrAlkalinity.RemarksOnResults
Acidity or alkalinity			
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Ph.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Ph.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Ph.ApplicantSummaryAndConclusion

2.6 Viscosity and surface tension

2.6.1 Viscosity

Viscosity - 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. viscosity

ENDPOINT_SUMMARY.Viscosity			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data summary – common block Conclude on the viscosity of the product/substance/preparation	Header 1	ENDPOINT_SUMMARY.Viscosity.AdministrativeDataSummary
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

Viscosity - Endpoint study record

Purpose
Viscosity 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.

ENDPOINT_STUDY_RECORD.Viscosity			
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 (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'.	Text area	ENDPOINT_STUDY_RECORD.Viscosity.MaterialsAndMethods.StandardCoveringTheApparatusUsed
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 'Illustration (picture/graph)'.		ENDPOINT_STUDY_RECORD.Viscosity.ResultsAndDiscussion.Viscosity
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.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 - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Viscosity.ResultsAndDiscussion.Viscosity.RemarksOnResults
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

2.6.2 Surface tension

Surface tension - 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. Surface tension

ENDPOINT_SUMMARY.SurfaceTension			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data summary – common block Conclude on the surface tension of the	Header 1	ENDPOINT_SUMMARY.SurfaceTension.AdministrativeDataSummary

	product/substance/preparation (state concentration, temperature and purity)		
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

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			
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)	Header 1	ENDPOINT_STUDY_RECORD.SurfaceTension.MaterialsAndMethods

	OECD Test Guideline 115: Surface tension of aqueous solutions are relevant for this endpoint		
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
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	ENDPOINT_STUDY_REC

		measure with Closed List (Decimal)	ORD.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
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

2.7 Technical characteristics of the plant protection product – Endpoint study record

Purpose
The technical characteristics of the plant protection product shall be determined and reported at appropriate concentrations.
The technical characteristics of the preparation must be determined to permit a decision to be made as to its acceptability.
If tests have to be performed, they must be done at temperatures compatible with survival of the micro-organism.

ENDPOINT_STUDY_RECORD.TechnicalCharacteristics			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data – common block This document can be used to report the following endpoints. Complete a separate document for each endpoint 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	Header 1	ENDPOINT_STUDY_RECORD.TechnicalCharacteristics.AdministrativeData
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_REC

			ORD.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

2.8 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			
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
	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	Closed list	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.DataSource.TypeOfCompatibility.Typ

	option. For microorganisms biological compatibility can also be indicated		eOfCompatibilityLabel
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
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.PhysicalChemicalCompatibility.ApplicantSummaryAndConclusion

2.9 Adherence and distribution to seeds, and additional physico-chemical information

Adherence and distribution to seeds, and additional physico-chemical information - 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			
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

Adherence and distribution to seeds, and additional physico-chemical information - 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			
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.AdditionalPhysicoC

			hemical.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 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)	Text area	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ResultsAndDiscussion.Results
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.OverallRemarks

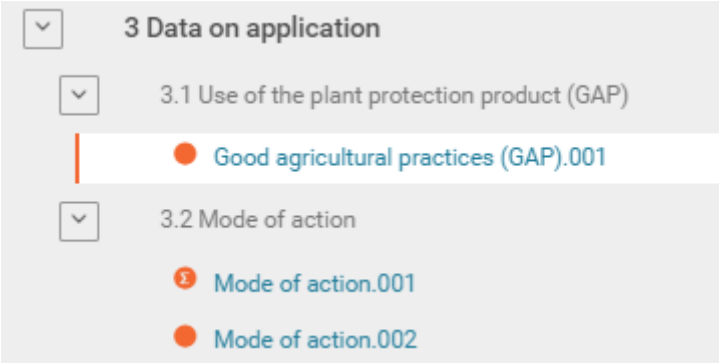
			Attachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalPhysicoChemical.ApplicantSummaryAndConclusion
Conclusions	Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation 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

3. Data on application

The following documents are located under section 3 "Data on application":

3.1 Use of the plant protection product (GAP) – Flexible record

3.2 Mode of action: Effectiveness against target organisms Endpoint summary / Endpoint study record



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.

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 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).	FLEXIBLE_RECORD.GAP.KeyInformation
Crop/treated object	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: • 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 Pisum sativum); • in brackets, the crop name in English is reported (PIBSX Pisum sativum (English pea); • for the most important crops, the corresponding	FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.Crop

	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 Pisum sativum (English pea) - 0260030, 0260040, 0300030). 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. 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. 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). 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. 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: • 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). 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	

<table>
<tr><td></td><td>parameters (see 1.3.6).
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 .
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:
<table>
<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></td><td></td></tr>
<tr><td>Genetical modification of crop</td><td>If relevant, describe variety of genetically modified crops on which the use of the plant protection product is intended to be used or authorised.</td><td>FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.GeneticalModification</td></tr>
<tr><td>Crop destination(s)</td><td>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</td><td>FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.CropDestination</td></tr>
<tr><td>Authorisation zone</td><td>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.</td><td>FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.AuthorisationZone</td></tr>
<tr><td>MRL zone</td><td>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/pestici</td><td>FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.MrlZone</td></tr>
</table>

	des_mrl_guidelines_app-d.pdf) (or a subsequent revision of this document).	
Country or territory	Select the country or the territory related to the GAP. The selection of more than one country is possible if the same GAP applies.	FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.CountryOrTerritory
Crop location (F/G/I)	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 prevents release of plant protection products into the environment. F: Fields and other structures which do not prevent release of plant protection products into the environment. 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.	FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.CropLocation
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	Select the appropriate code and scientific name from picklist. The picklist is based on the EPPO list (https://gd.eppo.int/taxon/). 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. If the target organism is not listed, select 'other' and specify. If a scientific name is not relevant or not known, select 'no data'. 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)'. Please make sure that the scientific name entered in this field matches with the organism described in the field	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.TargetOrganisms.ScientificName

	'Common name'.	
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	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). If no appropriate description is available in the list, select 'other:' and specify the development stage in the remarks. If the development stage is not known or not further specified, select 'not specified'. If the development stage is not relevant/applicable, leave field empty. Multiple selection of terms is allowed.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.TargetOrganisms.DevelopmentStagePest
Development stage of target plant	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.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.TargetOrganisms.DevelopmentStagePlant
Major/minor use	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).	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.MajorMinorUse
Application target	The target to be treated can be selected from a picklist. The following terms are implemented: **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	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationTarget

	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.
Agricultural Commodity	Post-harvest application to an agricultural product that can be bought and sold (*e.g.*, treatment to grain, fibre, cut flowers, packaged animal feed, *etc*).
Soil (surface)	Application to the ground in which plants can grow.
Soil (subsurface)	Application below the ground, or immediately incorporated.
Water	Application to water in systems, pools, pipes, tanks or other containers, or bodies of water, such as lakes, ponds, bays, estuaries, oceans, reservoirs.
Air	Application directed to a space, rather than a specific target. Examples of these types of applications include foggers, mosquitocides, ozone generators, knock-down insecticides, etc. This does not include aerial broadcast applications over a crop because the target is the crop, not the air over the crop.
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 Please select the most appropriate treatment target.	
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. 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.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationMethod
Growth stage and season	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.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason
Growth stage of crop (first application)	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).	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason.GrowthStageCropFirst

	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). 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.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationRatePerTreatment

	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).	
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
Water amount per treatment / spray volume	For products applied after dilution with water, the minimum and maximum amount of water used in spray application (spray volume) should be reported.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.WaterAmountPerTreatment
Concentration of formulation in dilution	For products applied after dilution with water, report the concentration of the formulation in the solution.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ConcentrationFormulationDilution
Safener/ synergist/ adjuvant added	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).	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.SafenerSynergistAdjuvant
Application rate per treatment for target a.s. (range)	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	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationRateForTarget

	(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).	
Maximum seasonal application rate (a.s.)	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. 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).	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.SeasonalAplication
Treatment window (for dispensers)	For dispensers or similar application forms, the duration of treatment window needs to be reported.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.TreatmentWindowDispensers
Seeding rate (maximum)	Field relevant for seed treatments only. 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 m^2. If 'other:' is selected as unit, describe the seeding rate unit in the remarks.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.MaxSeedingRate
Planting density	The field is not mandatory. Describe the planting density (number of plants per ha or m^2).	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.PlantingDensity
Pre-harvest interval	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	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.PreharvestInterval

	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'.	
Re-entry period livestock	The field is not mandatory. 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.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.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.: - 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,	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.Restrictions

	- restricted soil type, - restriction to crops grown in artificial substrate, - 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 Mode of action

Function and mode of control - Endpoint summary

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_SUMMARY.EffectivenessAgainstTargetOrganism			
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	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.AdministrativeDataSummary.DataProtection

	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants		
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.Discussion

Function and mode of control - Endpoint study record

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			
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 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	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.BackgroundInformation

	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. 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 block of fields. Any remarks can be entered in the supplementary remarks field, for instance any code for target organism	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.ScientificName

	if required so according to programme-specific guidance. If so, indicate 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 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		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgain

application			stTargetOrganisms.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 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.	Open list	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.ProductType
Field of use envisaged / User	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	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FieldOfUseEnvisagedUser
Information on application of biocidal product		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfBiocidalProduct
Method of application	See **Field of use envisaged / User**	Multi select open list with	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.Gen

		remarks (2000)	eralInformation.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 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'.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.EffectsOnTargetOrganisms

Mode of action	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..	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ModeAction
Details on mode of action	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	Text template	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.DetailsOnModeOfAction
(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		Header 1	ENDPOINT_STUDY_REC

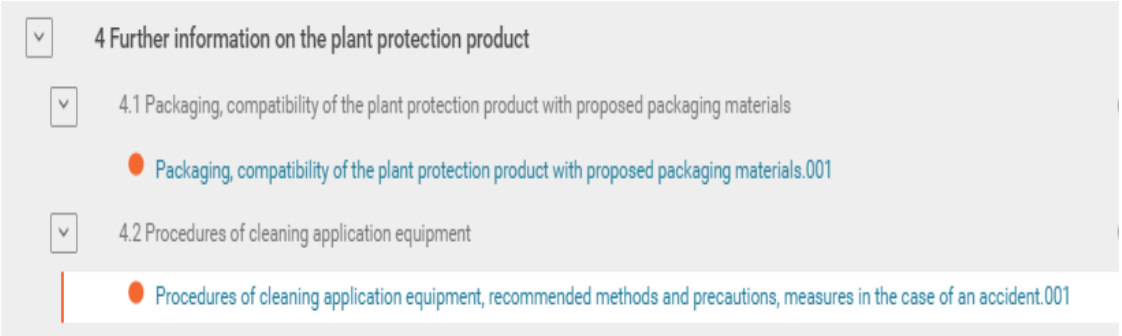
discussion			ORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion
Details on results		Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 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

The following documents are located under section 4 "Further information on the plant protection product:

4.1 Packaging, compatibility of the plant protection product with proposed packaging materials: Packaging - Flexible record

4.2 Procedures of cleaning application equipment: Protection measures – Flexible record



4.1 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.

FLEXIBLE_RECORD.Packaging			
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:	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. 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 family, this field remains	Endpoint reference list	FLEXIBLE_RECORD.Packaging.Packaging.UseOrComposition

	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 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).	Open list	FLEXIBLE_RECORD.Packaging.Packaging.MaterialOfPackaging
Compatibility of the product with the packaging materials proposed to be in contact with the product	This field is used to give any information that is needed to prove that the packaging material is compatible with the product.	Text area	FLEXIBLE_RECORD.Packaging.Packaging.Compatibility
Further description of the packaging in contact with the product	If needed, give any further explanations concerning the packaging being in contact with product.	Text area	FLEXIBLE_RECORD.Packaging.Packaging.FurtherDescription

Safety features of the packaging	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.).	Text area	FLEXIBLE_RECORD.Packaging.Packaging.SafetyFeaturesOfThePackaging
Description of the secondary packaging (not in contact with the product)	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.	Text area	FLEXIBLE_RECORD.Packaging.Packaging.Description
Packaging related attachments			FLEXIBLE_RECORD.Packaging.Packaging.PackagingRelatedAttachments
Type of attachment	This field is used to indicate the type of document which is attached. The option 'other' is available, with specification in the additional text field. This is the correct place to attach a picture of label of packaging.	Open list	FLEXIBLE_RECORD.Packaging.Packaging.PackagingRelatedAttachments.TypeOfAttachment
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

4.2 Procedures of cleaning application equipment – Flexible record

Purpose
The risks likely to arise and the methods and procedures to minimise the hazards arising, shall be specified.
Recommended methods and precautions.
Emergency measures in the case of an accident,
Procedures for destruction or decontamination
Neutralisation procedure
Controlled incineration
Procedures for cleaning application equipment

FLEXIBLE_RECORD.ProtectionMeasures			
Name	**Instructions**	**Data type**	**Field path**
Administrative data		Header 1	FLEXIBLE_RECORD.ProtectionMeasures.AdministrativeDataSummary
	See 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	Substance: The field is used to identify all methods and precautions concerning the storage of an active substance. 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.	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. Detailed handling procedures for the storage, at both warehouse and user level of plant protection products must be provided 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	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.RecommendedMethodsAndPrecautionsConcerningHandling

	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 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 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	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.EmergencyMeasuresToProtectEnvironmentInCaseOfAccident
Control measures of repellents or	The field is used to identify all measures that could be taken to	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.M

poison included in the product, to prevent action against non-target organisms (relevant for products only)	prevent action against non-target organisms when using the product.		easuresToProtect.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 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 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 procedures for industry or	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.Possibilit

	professional users. 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 Procedures to preclude or minimise the generation of waste or leftovers shall be provided.		yOfReuseOrRecycling
Neutralisation procedure and possibility of neutralisation of effects	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 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 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. 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.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.PossibilityOfNeutralisationOfEffects
Conditions for controlled discharge including leachate qualities on disposal	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	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.ConditionsForControllerDischarge

	professional users should be done. 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.		
Conditions for controlled incineration	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) 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. 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.	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
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	Literature reference list	FLEXIBLE_RECORD.ProtectionMeasures.AdditionalInformation.Reference

	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. 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 Safety datasheets in the form of literature references can be added as references in this field		

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

5. Analytical methods

The following documents are located under section 5 "Analytical methods":

Analytical methods Endpoint summary / Endpoint study record

Analytical methods - 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: 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)

ENDPOINT_SUMMARY.AnalyticalMethods			
Label	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block 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	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.AdministrativeDataSummary
Additional information	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.	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.Discussion

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.

ENDPOINT_STUDY_RECORD.AnalyticalMethods

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.DataSource.Reference
Background		Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.Background
Background 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_RECORD.AnalyticalMethods.Background.BackgroundInformation
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	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods

	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.		
Matrix / medium	Indicate the medium for which the analytical method is described. In the supplementary remarks field, you can add explanations as appropriate. 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.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.MatrixMedium
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.TestMaterials
Principles of analytical methods		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods
Instrument / detector	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'. 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	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods.InstrumentDetector

	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.		
Details on analytical 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.PrinciplesOfAnalyticalMethods.DetailsOnAnalyticalMethod
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
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	Any other information on materials and	Header 2	ENDPOINT_STUDY_REC

information on materials and methods incl. tables	methods incl. tables - (H2) – common block		ORD.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.') 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.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.RecoveryResults
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.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.CharacteristicsOfAnalyticalMethod

	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'. Note: Specific tables may be required.		
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 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.') 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	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.RecoveryResults

	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 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), 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: .....'). 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'). Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.CharacteristicsOfEnforcementMethod
Independent laboratory validation (if applicable)	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. '...	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation

	see Table 1'). Note: Specific tables may be required.		
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	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 materials

- SANCO/3029/99, Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414.

- SANCO/3030/99, 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.

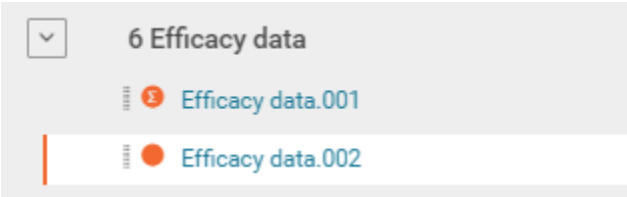
- SANCO/825/00, Guidance document on pesticide residue analytical methods

- SANCO/12116/2012, Working Document on Microbial Contaminant Limits for Microbial Pest Control Products

6. Efficacy data

The following documents are located under section 6 "Efficacy data":

Efficacy data Endpoint summary / Endpoint study record



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		
Field name	**Instructions**	**Field path**
Administrative data		ENDPOINT_SUMMARY.Efficacy .AdministrativeDataSummary
Description of key information	Enter a short description of key findings of the submitted studies including -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 Do the number of trials to be conducted and reported reflect factors such as the	ENDPOINT_SUMMARY.Efficacy .KeyInformation

	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 the type of harmful organism and the type of plant protection product? Statement on whether representative uses GAPs are supported.	
Additional information	Provide additional information related to the endpoint, for example: - 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. 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. Where appropriate a separate table should be included showing the results of any yielded crop safety trials should also be added If there is no additional information to be	ENDPOINT_SUMMARY.Efficacy .Discussion.Discussion

	reported this field may be left empty.	
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

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		
Field name	**Instructions**	**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 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. EPPO standard series PP1).	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.Guideline
Qualifier	Select appropriate qualifier, i.e. - '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').	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.Guideline.Qualifier
Guideline	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'. 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.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.Guideline.Guideline
Version / remarks	In this text field, you can enter any remarks as	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAn

	applicable, particularly: - 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.	dMethods.Guideline.Version Remarks
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 in square brackets [...] as appropriate. 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. 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.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.MethodNoGuideline
GLP compliance	Indicate whether the study was conducted following Good Laboratory Practice or not. In	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAn

	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.	dMethods.GLPComplianceStatement
Compliance with quality	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. In the supplementary remarks field, you can add explanations 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'.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.ComplianceWithQualityStandards
Test material		ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Formulation type	Indicate the type of formulation used in the study. If not listed, select 'other' and specify. 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.	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 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.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.TestTargetOrganisms
Scientific name	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. 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.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.TestTargetOrganisms.ScientificName
Common name	Select appropriate common name from picklist. If not listed, 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. Any remarks can be entered in the	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.TestTargetOrganisms.CommonName

	supplementary remarks field.	
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.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.TestTargetOrganisms.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. 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 used in analogy for the target plants.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.TestTargetOrganisms.DevelopmentalStageOfTargetPlant
Details on test / target organisms	**Freetext template:** **Option 1 For single species test** - Strain: - Source: - Wild type: [yes/no] - 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): **Option 2 For test with microbial**	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.PestTargetOrganismsToBeControlled.DetailsOnTestTargetOrganisms

	population / inoculum - Nature: - Origin: - Collection / storage of samples: - Preparation of inoculum for exposure: - Pretreatment: - Initial biomass / density / numbers in test system: - Other (specify):	
Products (materials), organisms or objects to be protected / under study		ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.ProductsMaterialsOrganismsOrObjectsToBeProtectedUnderStudy
Organisms (to be protected) or treated materials	If applicable, describe and specify the organism(s) or materials(s) / object(s) to be protected as addressed by these efficacy data.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.ProductsMaterialsOrganismsOrObjectsToBeProtectedUnderStudy.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	**Freetext template**: - Effects investigated: - Method for recording / scoring effects: - Intervals of examination: - Post monitoring of test organisms 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. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.StudyDesign.ModeOfEfficacyAssessment
Method of application	Indicate the method of application. If not listed, select 'other' and specify. Any remarks can be entered in the supplementary remarks field.	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.StudyDesign.MethodOfApplication
Details on study design	**Option 1 Optional items for laboratory studies** FURTHER DETAILS ON APPLICATION - Application/dosage and dilution rates (incl. dose justification): - Adjuvans/vehicle/carrier: - Presence of interfering substances: - Other (specify) MONITORING OF TEST SUBSTANCE - Monitoring of active substance concentration: - Method of analysis: TEST CHAMBER / DEVICE - Type and design of test chamber / device: - Other (specify)	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.StudyDesign.DetailsOnStudyDesign

	SURFACE TYPES - Type: [porous, non-porous] TEST CONDITIONS - 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) INITIAL DENSITY/NUMBERS OF TARGET ORGANISMS - Initial density / numbers in test system: - Frequency or level of infestation / infection: REPLICATES - Number of replicates: CONTROLS - Untreated controls: - Positive controls (reference substance): OTHER (specify): **Option 2 Optional items for field and use tests** APPLICATION - 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) EXPERIMENTAL DESIGN - GEOGRAPHICAL LOCATION - For efficacy evaluation the EPPO climatic zones should be mentioned TEST CONDITIONS / METEOROLOGICAL INFORMATION INITIAL DENSITY/NUMBERS OF TARGET ORGANISMS - Initial density / numbers in test system: - Frequency or level of infestation / infection: REPLICATES - Number of replicates: CONTROLS - Untreated controls: - Positive controls (reference substance): OTHER (specify):	
Any other information on materials and methods 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, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One	ENDPOINT_STUDY_RECORD.EfficacyData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation

	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.	
Results and discussion		ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion
Efficacy / performance assessment	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. 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.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.EfficacyPerformanceAssessment
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.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.EfficacyPerformanceAssessment.Treatment

	Specify dose, application rate, duration, etc.	
Interfering substances	Indicate if interfering substances were present. If 'yes' is selected, briefly specify in the supplementary remarks field.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.EfficacyPerformanceAssessment.InterferingSubstances
Remarks on result	- not determinable - not determinable because of methodological limitations - not measured/tested - other: 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:'.	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
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	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.MinimumEffectiveDose.TimeToProduceEffec

	together with the appropriate qualifier(s) if applicable.	t
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.MinimumEffectiveDose.Treatment
Interfering substances	Indicate if interfering substances were present. If 'yes' is selected, briefly specify in the supplementary remarks field.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.MinimumEffectiveDose.InterferingSubstances
Remarks on result	- not determinable - not determinable because of methodological limitations - not measured/tested - other: 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:'.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.MinimumEffectiveDose.RemarksOnResults
Details on results	RESULTS - Effects observed: - Dose/concentration dependence of effects: - Begin and duration of effectiveness: - Observed effects in post-monitoring phase: - Reinvasion/reinfestation: - Existence of threshold concentration:	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ResultsOnDetails

	- Other: REPORTED STATISTICS: REFERENCE SUBSTANCE - Results with reference substance: - Results with reference substance valid 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'. Note: Observed limitations on efficacy in terms of resistance, 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	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. Select 'not examined' or 'no data' as applicable.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.IndicationOfResistance
Details on development of resistance	Provide details on the development of resistance as observed in the efficacy study(ies), including any evidence of cross-resistance.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.DetailsOnDevelopmentOfResistance
Undesirable or unintended side	Indicate whether any undesirable or unintended side effects were observed or not. In below field	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAnd

effects	'Details on undesirable or unintended side effects', give details or provide any further explanation, e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Discussion.ObservedLimitationsOnEfficacy.UndesirableOrUnintendedSideEffects
Details on undesirable or unintended side effects	Provide details on undesirable or unintended side effects as observed in the efficacy study(ies). Where appropriate or required by the relevant legislation, insert subheadings, e.g.: -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:	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.DetailsOnUndesirableOrUnintendedSideEffects
Other limitations observed	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.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.OtherLimitationsObserved
Relevance of study results	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'). 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	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.ObservedLimitationsOnEfficacy.RelevanceOfStudyResults

	bridging arguments. Use freetext template and delete/add elements as appropriate.	
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.	ENDPOINT_STUDY_RECORD.EfficacyData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments		ENDPOINT_STUDY_RECORD.EfficacyData.OverallRemarksAttachments
Overall remarks	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. 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.	ENDPOINT_STUDY_RECORD.EfficacyData.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).	ENDPOINT_STUDY_RECORD.EfficacyData.OverallRemarksAttachments.AttachedBackgroundMaterial

	Copy this block of fields for attaching more than one file.	
Attached document	Provide any additional documents relevant for the submission, not already provided under the methods or results section or in the full study report. Examples are: - Scientific publication - GLP documentation - 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 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.	ENDPOINT_STUDY_RECORD.EfficacyData.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached	ENDPOINT_STUDY_RECORD.EfficacyData.OverallRem

	document if the file name is not self-explanatory.	arksAttachments.AttachedBackgroundMaterial.Remarks
Attached full study report	Please use the corresponding field under the Literature Reference entity to upload the full study report in pdf format.	ENDPOINT_STUDY_RECORD.EfficacyData.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.	ENDPOINT_STUDY_RECORD.EfficacyData.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication	Please use the corresponding field under the Literature Reference entity to upload the sanitised version of the full study report in pdf format.	ENDPOINT_STUDY_RECORD.EfficacyData.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion		ENDPOINT_STUDY_RECORD.EfficacyData.ApplicantSummaryAndConclusion
Key result	This read-only field displays the key results flagged in the corresponding results table(s), if any.	ENDPOINT_STUDY_RECORD.EfficacyData.ApplicantSummaryAndConclusion.KeyResult
Conclusions	Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any).	ENDPOINT_STUDY_RECORD.EfficacyData.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	ENDPOINT_STUDY_RECORD.EfficacyData.ApplicantSummaryAndConclusion.ExecutiveSummary

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

7. Effects on human health

The following documents are located under section 7 "Effects on human health":

7. Effects on human health – Endpoint summary

7.1 Basic acute toxicity studies – Endpoint summary

7.1.1 Acute oral toxicity – Endpoint study record

7.1.2 Acute inhalation toxicity – Endpoint study record

7.1.3 Acute percutaneous toxicity – Endpoint study record

7.2 Additional acute toxicity studies

7.2.1 Irritation – Endpoint summary

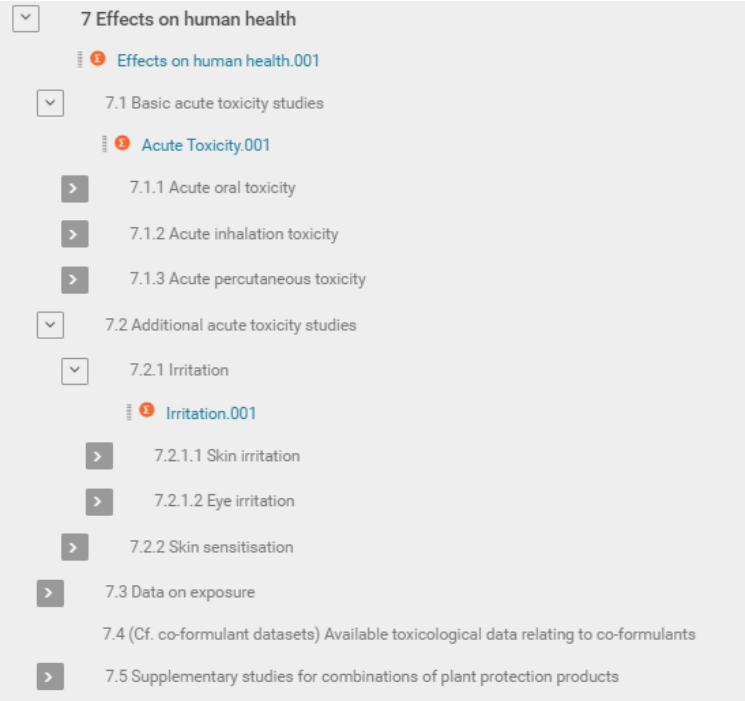
7.2.1.1 Skin irritation – Endpoint study record

7.2.1.2 Eye irritation – Endpoint study record

7.2.2 Skin sensitization: Sensitization Endpoint summary / Skin sensitization Endpoint study record

7.3 Data on exposure – Flexible summary

7.5 Supplementary studies for combinations of plant protection products – Endpoint study record



Effects on human health - 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.

ENDPOINT_SUMMARY.AdditionalToxicologicalInformation			
Name	**Instructions**	**Type**	**Field Path**

Administrative data	Administrative data summary – common block Provide a brief description of additional toxicological studies and effects.	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: - 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. If there is no additional information to be reported this field may be left empty. *See IUCLID templates for PPP Risk Assessment - Template 5.4 - Template summary table on the assessment of the toxicological profile of metabolites* [http://doi.org/10.5281/zenodo.4557353]"	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.Discussion

7.1 Basic acute toxicity 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 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			
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 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.AcuteToxicityViaOralRoute.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	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute.EndpointConclusi

	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.		on
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 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.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.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	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute.LinkToRelevantStudyRecords

	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.AcuteToxicityViaDermalRoute.EndpointConclusion
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

7.1.1 Acute 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 assesment 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 only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008.

ENDPOINT_STUDY_RECORD.AcuteToxicityOral			
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	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	Open list	ENDPOINT_STUDY_RECORD.AcuteToxici

	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.		tyOral.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. 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.	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. 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.MaterialsAnd

			Methods.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 in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
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	Summarise evidence of toxicity and mortality of any	Multi-	ENDPOINT_STUDY_

study	preliminary sighting study.	line text	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 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'.		ENDPOINT_STUDY_RECORD.AcuteToxicityOral.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.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. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.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.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	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.ClinicalSigns

	no obvious substance-related signs of toxicity.		
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
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
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ApplicantSummaryAndConclusion

7.1.2 Acute inhalation toxicity – 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 × 10–2 Pa at 20 °C;
- the active substance is a powder containing a significant proportion of particles of a diameter < 50 µm (> 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			
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 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.	Closed 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
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	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter

	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. 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'.	Closed 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 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.AcuteToxicityInhal

			ation.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.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhal

on materials and methods incl. tables	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		ation.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.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.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 concentration was used, select 'discriminating conc.', i.e the dose causing evident toxicity but not mortality. 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	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.Endpoint

	reported as appropriate with relevant qualifier, e.g. LC50 >10 mg/m³ air or LC50 <10 mg/m³ air. For micro-organisms (CFU/L air or some other units should be used) 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.AcuteToxicityInhalation.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.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if relevant 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.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.cl
Exp. duration	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.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.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	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.RemarksOnResults

	determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'		
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
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	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.OtherFindings

	organs/tissues, if any		
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

7.1.3 Acute percutaneous 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			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.AdministrativeData
Data	Data source (Literature Reference) – common block	Head	ENDPOINT_STUDY_R

source		er 1	ECORD.AcuteToxicity Dermal.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.AcuteToxicity Dermal.MaterialsAnd Methods
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.AcuteToxicity Dermal.MaterialsAnd Methods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicity Dermal.MaterialsAnd Methods.LimitTest
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicity Dermal.MaterialsAnd Methods.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. 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'.	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicity Dermal.MaterialsAnd Methods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicity Dermal.MaterialsAnd Methods.AdministrationExposure
Type of	Select type of coverage used. For robust study summaries	Ope	ENDPOINT_STUDY_R

coverage	specify the area of application in field 'Details on dermal exposure'.	n list	ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.TypeOfC overage
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.	Ope n list with rema rks	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.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 temp late	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.DetailsO nDermalExposure
Duration of exposure	Indicate total duration of exposure in hours, e.g. '4 hrs'.	Multi -line text	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.Duration OfExposure
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 temp late	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.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_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.NoOfAni malsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable.	Ope n list with rema rks	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.ControlA nimals
Details on	Include any further details on the study design, i.e.	Text	ENDPOINT_STUDY_R

study design	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.	template	ECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
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.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.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	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.Endpoint

	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'.		
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

	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
Applicant's summary and conclusio	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ApplicantSummaryAndConclusion

n			

7.2 Additional acute toxicity studies

7.2.1 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

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	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSaf

	(Category 2). "Adverse effect observed (corrosive)" should be chosen if the substance meets the classification criteria for skin corrosion (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.		etyAssessment.SkinIrritationCorrosion.EndpointConclusion.EndpointConclusion
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 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.	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.EndpointConclusion.EndpointConclusion
Respiratory irritation		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation
Endpoint		Header 3	ENDPOINT_SUMMARY

conclusion			.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion
Endpoint conclusion	"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.	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion.EndpointConclusion
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

7.2.1.1 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			
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	Material and methods – common block Applicable test guideline: Method B.4 Acute toxicity: dermal irritation/corrosion (Annex to Regulation (EC) No 440/2008). OECD TG 430 / Method B.40 In vitro skin corrosion: transcutaneous electrical resistance test (TER) (Annex to Regulation (EC) No 440/2008). OECD TG 431 / Method B.40 bis In vitro skin corrosion: human skin model test (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 404: Acute Dermal Irritation/Corrosion OECD Test Guideline 431: In vitro Skin Corrosion: Human Skin Model Test OECD Test Guideline 430: In vitro Skin Corrosion: Transcutaneous Electrical Resistance Test OECD Test Guideline 435: In vitro Membrane Barrier Test Method for Skin Corrosion OECD Test Guideline 439: In vitro Skin Irritation: Reconstructed Human Epidermis Test Method OECD TG 439 / Method B.46 In vitro skin irritation: reconstructed human epidermis model test (Annex III of Regulation (EC) No 761/2009 (7).	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestMaterials
In vitro test system		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMe

			thods.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. - 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.JustificationForTestS

			ystemUsed
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 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. Explanations: - 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 ³ 10 kΩ) - 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	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DetailsOnTestSystem

	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) - 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.MaterialsAndMe

			thods.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. 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.	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 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 /	Give the amount(s) of substance applied (volume or	Text	ENDPOINT_STUDY_RE

concentration applied	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.	template	CORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.AmountConcentrationApplied
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_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.DurationOfTreatmentExposure
Observation period	Indicate length of observation period.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.ObservationPeriod
Number of animals	Indicate number of animals used.	Multi-line text	ENDPOINT_STUDY_RECORD.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_RECORD.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_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	Indicate the overall irritation / corrosion results for the test substance in terms of tissue viability, transcutaneous electrical resistance, penetration time or other. Copy this		ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscu

	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 "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.		ssion.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.IritationCorrosionParameter
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 iritation/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	Indicate whether test with positive control(s) is valid, i.e.	Open	ENDPOINT_STUDY_RE

controls validity	substance(s) with known iritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	list with remarks	CORD.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
In vivo		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo
Results	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		ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results

	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. 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". 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 rema	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Re

		rks	versibility
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
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.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. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In	Rich text area	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation

	addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.		
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ApplicantSummaryAndConclusion

7.2.1.2 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			
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	Material and methods – common block Applicable test guideline:	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritatio

methods	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		n.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
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 environme	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	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.OrganismDetails

ntal conditions	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).		
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, lo/batch No. including expirations 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
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	Indicate length of post-treatment incubation period as appropriate.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMeth

incubation (in vitro)			ods.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
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 entering the adequate qualitative description of the		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy

	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 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	Open list with rema	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOf

	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:'.	rks (2000)	ExVivoInVitroStudy.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 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		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults

	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. 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 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	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.RemarksOnResults

	selecting 'other:'.		
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		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.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. 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.	Rich text area	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
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

7.2.2 Skin sensitisation

Skin sensitisation - 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			
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: 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.KeyValueForChemicalSafetyAssessm

			ent.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" is chosen, a justification needs to be provided.	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.EndpointConclusion
Additional information	Provide additional information related to the endpoint, for example: - 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. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.AdditionalInformation
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.	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisa

	"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.		tion.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

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			
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). OECD 429 OECD 442A + 442B.	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.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 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.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.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.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		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.

test system			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 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'. 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-	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Species

	reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.		
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	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 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
Route	Indicate the route of induction exposure.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.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	Open list with remar	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyD

	rationale should be provided.	ks	esignInVivoNonLLNA.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_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.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	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.	Closed 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, 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 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	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.DetailsOnStudyDesign

	- 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		
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.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).	Closed 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 relevant for evaluating this study summary or that are requested by the respective regulatory programme. - Details on radio isotope: to be included in field 'Details	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.DetailsOnStudyDesign

	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). MAIN STUDY - 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).		
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.	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

tables			
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
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	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.

	remarks field. Please include EC150 and EC200 values, if those can be calculated.	with remarks	ResultsAndDiscussion.InVitroInChemico.Results.Parameter
Value	Indicate also the unit of measurement e.g. µM, mM, µg/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 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'. - 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. 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.		ENDPOINT_STUDY_RECORD.SkinSensitisation.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.TraditionalSensitisationT

			est.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
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	Open list with remar	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationT

	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:'	ks (2000)	est.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 results incl. 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.		ENDPOINT_STUDY_RECORD.SkinSensitisation.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-animal variability in both the test substance and control groups when using the individual animal approach.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.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 incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
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

7.3 Data on exposure – Endpoint summary

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).

FLEXIBLE_SUMMARY.NonDietaryExpo			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.NonDietaryExpo.AdministrativeDataSummary
	See Confidentiality request	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	Enter a short description of the most	Header 1	FLEXIBLE_SUMMARY.NonDie

of key information	relevant summary data. EFSA Guidance on Non-Dietary exposure, 2014, DOI:10.2903/j.efsa.2014.3874 can be consulted when preparing this summary.		taryExpo.KeyInformation
		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			
Additional information	Discussion (Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.NonDietaryExpo.Discussion
	Provide additional information related to the endpoint, for example: - 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. If there is no additional information to be reported this field may be left empty.	Rich text area	FLEXIBLE_SUMMARY.NonDietaryExpo.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.NonDietaryExpo.Discussion.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. The excel calculator from the EFSA Guidance (2014) should be provided.	Single file attachment	FLEXIBLE_SUMMARY.NonDietaryExpo.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a	Text	FLEXIBLE_SUMMARY.NonDie

	short description of the content of the attached document if the file name is not self-explanatory		taryExpo.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.NonDietaryExpo.Discussion.AttachedSanitisedDocsForPublication

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

7.5 Supplementary studies for combinations of plant protection products – 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			
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.DataSource
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. 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, hematoxicity, hepatotoxicity, mechanistic studies, methaemoglobinaemia, nephrotoxicity, phototoxicity, respiratory irritation, splenic toxicity, or toxicogenomics.	Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.TypeOfStudyInformation
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.ResultsA

			ndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
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

9. Fate and behaviour in the environment

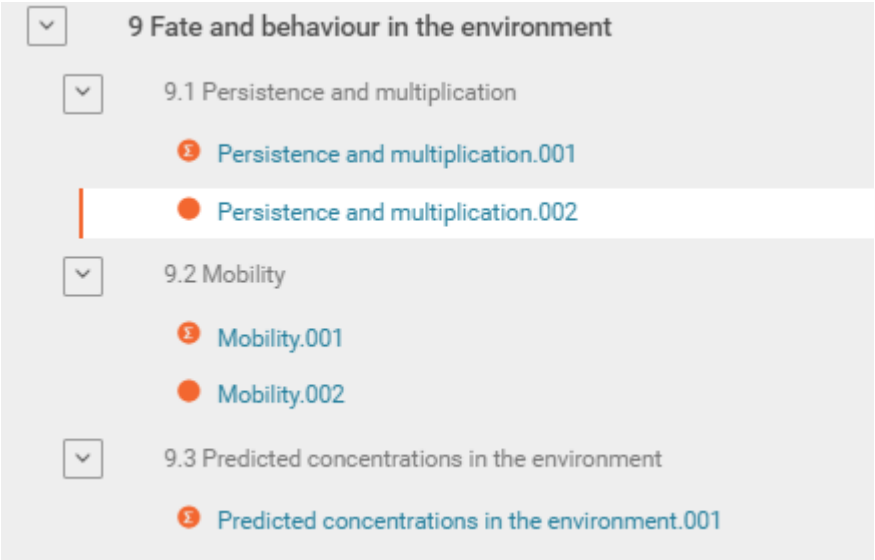
The following documents are located under section 9 "Fate and behaviour in the environment":

9. Fate and behaviour in the environment – Endpoint summary

9.1 Persistence and multiplication: Additional information on environmental fate and behaviour Endpoint summary / Endpoint study record

9.2 Mobility: Other distribution data Endpoint summary / Endpoint study record

9.3 Predicted concentrations in the environment – Endpoint summary



Fate and behaviour 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

ENDPOINT_SUMMARY.EnvironmentalFateAndPathways			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data summary – common block 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 orginal file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.Discussion

9.1 Persistence and multiplication

Persistence and multiplication - 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 persistence and multiplication (competitiveness) in soil, water and air.

ENDPOINT_SUMMARY.AdditionalInformationOnEnvironmentalFateAndBehaviour			
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

Persistence and multiplication -- Endpoint study record

Purpose
Where relevant, appropriate information on the persistence and multiplication of the micro-organism, in all environmental compartments has to be given, unless it can be justified that exposure of the particular environmental compartment to the micro-organism is unlikely to occur. Special attention shall be given to

- competitiveness under the environmental conditions prevailing at and after the intended use, and
- population dynamics in seasonally or regionally extreme climates (particularly hot summer, cold winter and rainfall) and to agricultural practices applied after intended use.

Estimated levels of the specified micro-organism in a time course after use of the product under the proposed conditions of use shall be given.

ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour			
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.AdditionalInformationOnEnvironmentalFateAndBehaviour.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInformati

			onOnEnvironmentalFate AndBehaviour.Materials AndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_REC ORD.AdditionalInformati onOnEnvironmentalFate AndBehaviour.Materials AndMethods.TestMateri als
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_REC ORD.AdditionalInformati onOnEnvironmentalFate AndBehaviour.Materials AndMethods.TestMateri als.TestMaterialInformat ion
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.AdditionalInformati onOnEnvironmentalFate AndBehaviour.Materials AndMethods.AnyOtherIn formationOnMaterialsAn dMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_REC ORD.AdditionalInformati onOnEnvironmentalFate AndBehaviour.ResultsAn dDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_REC ORD.AdditionalInformati onOnEnvironmentalFate AndBehaviour.ResultsAn dDiscussion.AnyOtherInf ormationOnResultsInclT ables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_REC ORD.AdditionalInformati onOnEnvironmentalFate AndBehaviour.OverallRe marksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_REC ORD.AdditionalInformati onOnEnvironmentalFate AndBehaviour.Applicant SummaryAndConclusion

9.2 Mobility

Mobility - 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			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block Provide a brief description of relevant studies and effects.	Header 1	ENDPOINT_SUMMARY.OtherDistributionData.AdministrativeDataSummary
Additional information	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 If there is no additional information to be reported this field may be left empty.	Header 1	ENDPOINT_SUMMARY.OtherDistributionData.Discussion

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)

Mobility - 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			
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.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

9.3 Predicted concentrations in the environment – Flexible summary

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.

This document can also be used to report predicted environmental concentrations for microorganisms and its metabolites.

FLEXIBLE_SUMMARY.EstConcOtherRoutes			
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		Endpoint	FLEXIBLE_SUMMARY.EstConcOthe

used as input parameters		reference list	rRoutes.RelevantSummaries.Input Summaries
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
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. Effects on non-target organisms

The following documents are located under section 10 "Effects on non-target organisms":

10 Effects on non-target organisms – Endpoint summary

10.1 Effects on birds: Toxicity to birds EU_PPP Endpoint summary / Toxicity to birds Endpoint study record

10.2 Effects on aquatic organisms – Endpoint summary

10.2.1 Short-term toxicity to fish: Short-term toxicity to fish EU_PPP Endpoint summary / Short-term Toxicity to birds Endpoint study record

10.2.2 Long-term and chronic toxicity to fish: Long-term toxicity to fish EU_PPP Endpoint summary / Long-term Toxicity to birds Endpoint study record

10.2.3 Short-term toxicity to aquatic invertebrates: Short-term toxicity to aquatic invertebrates EU_PPP Endpoint summary / Short-term toxicity to aquatic invertebrates Endpoint study record

10.2.4 Long-term and chronic toxicity to aquatic invertebrates: Long-term toxicity to aquatic invertebrates EU_PPP Endpoint summary / Long-term toxicity to aquatic invertebrates Endpoint study record

10.2.5 Effects on algal growth: Toxicity to aquatic algae and cyanobacteria EU_PPP Endpoint summary / Toxicity to aquatic algae and cyanobacteria Endpoint study record

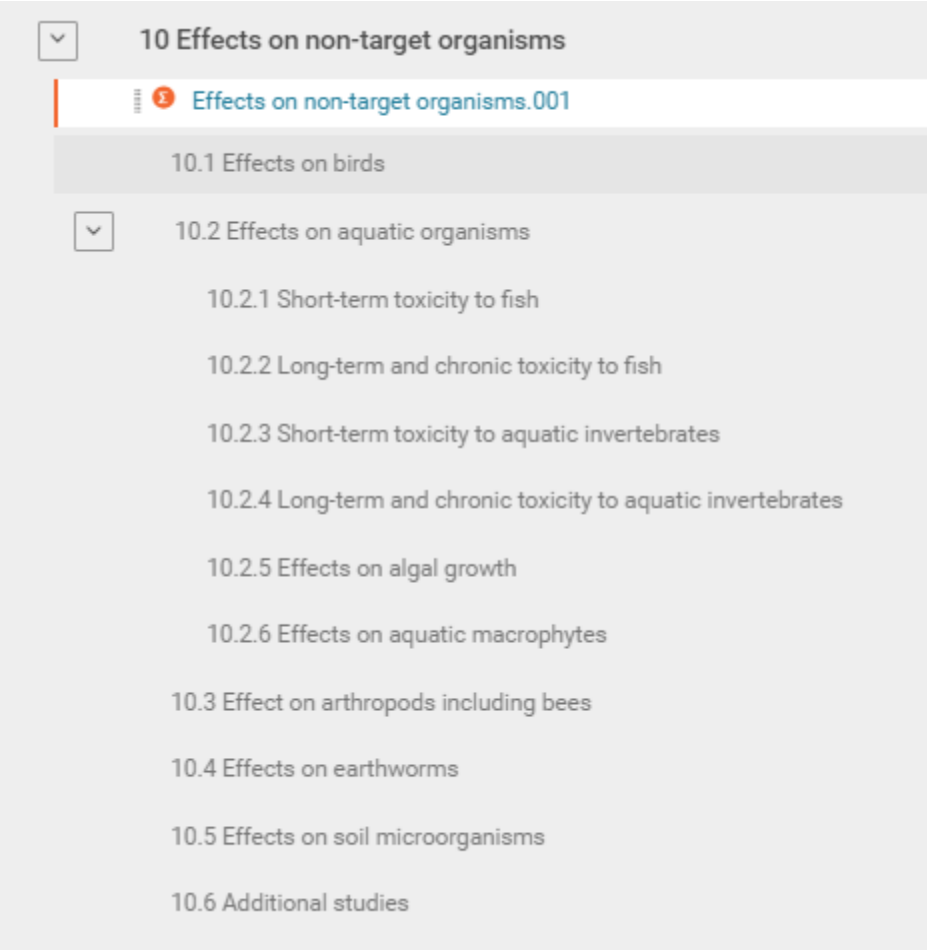
10.2.6 Effects on aquatic macrophytes: Toxicity to plants EU_PPP Endpoint summary / Toxicity to plants Endpoint study record

10.3 Effect on arthropods including bees: Toxicity to terrestrial arthropods EU_PPP Endpoint summary / Toxicity to terrestrial arthropods Endpoint study record

10.4 Effects on earthworms: Toxicity to soil macroorganisms except arthropods EU_PPP Endpoint summary / Toxicity to soil macroorganisms except arthropods Endpoint study record

10.5 Effects on soil microorganisms: Toxicity to soil microorganisms (EU PPP) Endpoint summary / Toxicity to soil microorganisms Endpoint study record

10.6 Additional studies: Toxicity to terrestrial plants Endpoint summary / Endpoint study record



Effects on non-target organisms - 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:

- Group: Specify species
- Time scale
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)

ENDPOINT_SUMMARY.EcotoxicologicalInformation			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.Ecotoxicological Information.AdministrativeDataSu

			mmary
Hazard for aquatic organisms		Header 1	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms
Freshwater		Header 2	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.Freshwater
Hazard assessment conclusion	Enter a PNEC value if possible (most common situation) If no PNEC is reported, a standard justification can be selected from the picklist: - Insufficient hazard data available (further information necessary] may be chosen for instance if no acute data is available and a testing proposal is made for a long term test. In such case a qualitative assessment will have to be carry out while waiting for the data; - "no data: aquatic toxicity unlikely" may be chosen for instance if the substance is unlikely to cross biological membranes. In such case it is assumed that toxicity can be excluded and no exposure assessment is needed - "no data available: testing technically not feasible" may be chosen if it is technically not possible to test the substance as a consequence of its properties: e.g. if it is highly reactive or unstable or when mixing of the substance with water may cause danger of fire or explosion. In such case a qualitative assessment will have to be carry out - "no hazard identified" may be chosen if no adverse effects have been identified up to the limit test concentrations recommended for the reported experimental studies or if there are other evidence that no hazard can be expected. In such case no exposure assessment is needed. In addition to those standard statements, a more detailed explanation on the reasons why no PNEC is provided should be reported in the 'Explanation on the hazard conclusion' field.	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.Freshwater.HazAssessConcl
PNEC value	PNEC value with unit.	Unit	ENDPOINT_SUMMARY.E

		measure with Closed List (Decimal)	cotoxicologicalInformation.HazardForAquaticOrganisms.Freshwater.HazAssessConclVal
Assessment factor	Specify the assessment factor used for deriving the PNEC (only whole number allowed). If a non-default assessment factor is used, a justification should be provided in the "Explanations on the hazard conclusion" field.	Decimal	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.Freshwater.AssessmentFactor
Extrapolation method	Select from the picklist the extrapolation method used for deriving the PNEC. The assessment factor method is the only applicable method for most of the substances. The species sensitivity distribution method can potentially be applied, only if at least 10 long-term data (and preferably more than 15) are available for different species covering at least 8 taxonomic groups.	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.Freshwater.ExtrapolationMethod
PNEC freshwater (intermittent releases)	PNEC value with unit. Intermittent releases are defined as occurring infrequently, i.e. less than once per month and for no more than 24 hours, for example as the result of batch processes. Intermittent releases are not applicable to widespread uses. A specific PNEC may be derived for intermittent releases. It is then normally calculated by applying an assessment factor of 100 to the lowest acute toxicity data of at least 3 trophic levels.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.Freshwater.PNECFreshwaterIntermittentReleases
Explanation for hazard conclusion	When a PNEC is derived, • if it is derived using assessment factors, specify the data which have been used for its derivation, e.g. justify the selection of data amongst the different taxonomic groups and justify the assessment factor used, when needed. • When the statistical extrapolation method is used, report information on the data used (including a description of the representativeness of the different taxonomic groups) and the distribution model used (including information on goodness of fit).	Rich text area	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.Freshwater.Justification

	When no PNEC is derived, provide an explanation on the hazard conclusion chosen. Provide any additional information related to the hazard conclusion.		
Marine water		Header 2	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.MarineWater
Hazard assessment conclusion	Enter a PNEC value if possible (most common situation) If no PNEC is reported, a standard justification can be selected from the picklist: - Insufficient hazard data available (further information necessary] may be chosen for instance if no acute data is available and a testing proposal is made for a long term test. In such case a qualitative assessment will have to be carry out while waiting for the data; - "no data: aquatic toxicity unlikely" may be chosen for instance if the substance is unlikely to cross biological membranes. In such case it is assumed that toxicity can be excluded and no exposure assessment is needed - "no data available: testing technically not feasible" may be chosen if it is technically not possible to test the substance as a consequence of its properties: e.g. if it is highly reactive or unstable or when mixing of the substance with water may cause danger of fire or explosion. In such case a qualitative assessment will have to be carry out - "no hazard identified" may be chosen if no adverse effects have been identified up to the limit test concentrations recommended for the reported experimental studies or if there are other evidence that no hazard can be expected. In such case no exposure assessment is needed. In addition to those standard statements, a more detailed explanation on the reasons why no PNEC is provided should be reported in the 'Explanation on the hazard conclusion'	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.MarineWater.HazAssessConcl
PNEC value	PNEC value with unit.	Unit	ENDPOINT_SUMMARY.E

		measure with Closed List (Decimal)	cotoxicologicalInformation.HazardForAquaticOrganisms.MarineWater.HazAssessConclVal
Assessment factor	Specify the assessment factor used for deriving the PNEC (only whole number allowed). It is assumed that the greater species diversity in the marine environment, compared to freshwaters, including the presence of a number of taxa that occur only in the marine environment, implies a higher uncertainty in extrapolation and therefore higher assessment factors unless data on saltwater species are available. If a non-default assessment factor is used, a justification should be provided in the "Explanations on the hazard conclusion" field.	Decimal	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.MarineWater.AssessmentFactor
Extrapolation method	Select from the picklist the extrapolation method used for deriving the PNEC. The assessment factor method is the only applicable method for most of the substances. The species sensitivity distribution method can potentially be applied, only if at least 10 long-term data (and preferably more than 15) are available for different species covering at least 8 taxonomic groups.	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.MarineWater.ExtrapolationMethod
PNEC marine water (intermittent releases)	Intermittent releases are defined as occurring infrequently, i.e. less than once per month and for no more than 24 hours, for example as the result of batch processes. Intermittent releases are not applicable to widespread uses. A specific PNEC may be derived for intermittent releases. It is assumed that the greater species diversity in the marine environment, compared to freshwaters, including the presence of a number of taxa that occur only in the marine environment, implies a higher uncertainty in extrapolation and therefore higher assessment factors unless data on saltwater species are available. The PNEC for intermittent releases in the marine	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.MarineWater.PNECMarineWaterIntermittentReleases

	water is then normally calculated by applying an assessment factor of 1000 to the lowest acute toxicity data of at least 3 trophic levels, or by applying an assessment factor of 100 to the lowest acute toxicity data covering at least 3 trophic levels (algae, crustaceans and fish) and two additional marine taxonomic groups (e.g. echinoderms, molluscs).		
Explanation for hazard conclusion	When a PNEC is derived, • if it is derived using assessment factors, specify the data which have been used for its derivation, e.g. justify the selection of data amongst the different taxonomic groups and justify the assessment factor used, when needed. • When the statistical extrapolation method is used, report information on the data used (including a description of the representativeness of the different taxonomic groups) and the distribution model used (including information on goodness of fit). When no PNEC is derived, provide an explanation on the hazard conclusion chosen. Provide any additional information related to the hazard conclusion.	Rich text area	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.MarineWater.Justification
STP		Header 2	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.STP
Hazard assessment conclusion	Enter a PNEC value if possible (most common situation) If no PNEC is reported, a standard justification can be selected from the picklist: - "no data: aquatic toxicity unlikely" may be chosen for instance if the substance is highly insoluble in water. - "no emission to STP expected" may be chosen for instance when there is no aqueous releases (e.g. dry process) for all the uses of the substance. Such conditions of use will have to be reported in all the exposure scenarios. - "no data available: testing technically not feasible" may be chosen if it is	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.STP.HazAssessConcl

	technically not possible to test the substance as a consequence of its properties: e.g. if it is highly reactive or unstable or when mixing of the substance with water may cause danger of fire or explosion. - "no hazard identified" may be chosen if no adverse effects have been identified up to the limit test concentrations recommended for the reported experimental studies. In addition to those standard statements, a more detailed explanation on the reasons why no PNEC is provided should be reported in the 'Explanation on the hazard conclusion' field.		
PNEC value	PNEC value with unit.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.STP.HazAssessConclVal
Assessment factor	Specify the assessment factor used for deriving the PNEC (only whole number allowed). If a non-default assessment factor is used, a justification should be provided in the "Explanations on the hazard conclusion" field.	Decimal	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.STP.AssessmentFactor
Extrapolation method		Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.STP.ExtrapolationMethod
Explanation for hazard conclusion	Specify the data which have been used for the derivation of the PNEC, e.g. justify the selection of data and justify the assessment factor used. When no PNEC is derived, provide an explanation on the hazard conclusion chosen. Provide any additional information related to the hazard conclusion.	Rich text area	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.STP.Justification
Sediment (freshwater)		Header 2	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.SedimentFreshWater

Hazard assessment conclusion	Enter a PNEC value if possible (most common situation) If no PNEC is reported, a standard justification can be selected from the picklist: - "no or insufficient data available at present" may be chosen for instance no data are available on sediment organisms and a hazard conclusion cannot be derived from the data available for aquatic organisms - "no exposure of sediment expected" may be chosen for instance when direct and indirect exposure of sediment is unlikely because there is no direct or indirect release to water for all the uses of the substance. Such conditions of use will have to be reported in all the exposure scenarios. - "no data available: testing technically not feasible" may be chosen if it is technically not possible to test the substance as a consequence of its properties: e.g. if it is very volatile, highly reactive or unstable or when mixing of the substance with water may cause danger of fire or explosion. - "no hazard identified" may be chosen if no adverse effects have been identified up to the limit test concentrations recommended for the reported experimental studies or if no hazard have been identified for aquatic organisms and, based on the properties of the substance it can be justified that no hazard is expected on sediment organisms. In addition to those standard statements, a more detailed explanation on the reasons why no PNEC is provided should be reported in the "Explanation on the hazard conclusion" field.	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.SedimentFreshWater.HazAssessConcl
PNEC value	PNEC value with unit.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.SedimentFreshWater.HazAssessConclVal
Assessment factor	Specify the assessment factor used for	Decimal	ENDPOINT_SUMMARY.E

	deriving the PNEC (only whole number allowed) This field does not need to be filled –in if the equilibrium partitioning method has been used. If a non-default assessment factor is used, a justification should be provided in the "Explanations on the hazard conclusion" field.		cotoxicologicalInformation.HazardForAquaticOrganisms.SedimentFreshWater.AssessmentFactor
Extrapolation method	Select from the picklist the extrapolation method used for deriving the PNEC. The assessment factor method is applicable if results from tests with sediment-dwelling organisms are available. The species sensitivity distribution method can potentially be applied only if at least 10 long-term data (and preferably more than 15) are available for different species covering at least 8 taxonomic groups. In the absence of any ecotoxicity data for sediment-dwelling organisms, the PNEC may be calculated from data on pelagic organisms using the equilibrium partitioning method (EPM).	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.SedimentFreshWater.ExtrapolationMethod
Explanation for hazard conclusion	When a PNEC is derived, • if it is derived using assessment factors, specify the data which have been used for its derivation, e.g. justify the selection of data amongst the different taxonomic groups and justify the assessment factor used, when needed. • When the statistical extrapolation method is used, report information on the data used (including a description of the representativeness of the different taxonomic groups) and the distribution model used (including information on goodness of fit). When the partitioning coefficient method is applied provide details on the model applied and input parameters. When no PNEC is derived, provide an explanation on the hazard conclusion chosen. Provide any additional information related to the hazard conclusion.	Rich text area	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.SedimentFreshWater.Justification
Sediment (marine		Header 2	ENDPOINT_SUMMARY.E

water)			cotoxicologicalInformation.HazardForAquaticOrganisms.SedimentMarineWater
Hazard assessment conclusion	Enter a PNEC value if possible (most common situation) If no PNEC is reported, a standard justification can be selected from the picklist: - "no or insufficient data available at present" may be chosen for instance no data are available on sediment organisms and a hazard conclusion cannot be derived from the data available for aquatic organisms. - "no exposure of sediment expected" may be chosen for instance when direct and indirect exposure of marine sediment is unlikely because there is no direct or indirect release to water for all the uses of the substance. Such conditions of use will have to be reported in all the exposure scenarios. - "no data available: testing technically not feasible" may be chosen if it is technically not possible to test the substance as a consequence of its properties: e.g. if it is very volatile, highly reactive or unstable or when mixing of the substance with water may cause danger of fire or explosion. - "no hazard identified" may be chosen if no adverse effects have been identified up to the limit test concentrations recommended for the reported experimental studies or if no hazard have been identified for aquatic organisms and, based on the properties of the substance it can be justified that no hazard is expected on sediment organisms. In addition to those standard statements, a more detailed explanation on the reasons why no PNEC is provided should be reported in the "Explanation on the hazard conclusion" field.	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.SedimentMarineWater.HazAssessConcl
PNEC value	PNEC value with unit.	Unit measure with	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrg

		Closed List (Decimal)	anisms.SedimentMarineWater.HazAssessConclVal
Assessment factor	Specify the assessment factor used for deriving the PNEC (only whole number allowed). This field does not need to be filled –in if the equilibrium partitioning method has been used. It is assumed that the greater species diversity in the marine environment, compared to freshwaters, including the presence of a number of taxa that occur only in the marine environment, implies a higher uncertainty in extrapolation and therefore higher assessment factors unless data on saltwater species are available. If a non-default assessment factor is used, a justification should be provided in the "Explanations on the hazard conclusion" field.	Decimal	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.SedimentMarineWater.AssessmentFactor
Extrapolation method		Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.SedimentMarineWater.ExtrapolationMethod
Explanation for hazard conclusion	When a PNEC is derived, • if it is derived using assessment factors, specify the data which have been used for its derivation, e.g. justify the selection of data amongst the different taxonomic groups and justify the assessment factor used, when needed. • When the statistical extrapolation method is used, report information on the data used (including a description of the representativeness of the different taxonomic groups) and the distribution model used (including information on goodness of fit). When the partitioning coefficient method is applied provide details on the model applied and input parameters. When no PNEC is derived, provide an explanation on the hazard conclusion	Rich text area	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAquaticOrganisms.SedimentMarineWater.Justification

	chosen. Provide any additional information related to the hazard conclusion.		
Hazard for air		Header 1	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAir
Air		Header 2	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAir.Air
Hazard assessment conclusion	A PNEC for air usually refers to exposure of plants via air. This kind of data will be extremely rarely available. Qualitative considerations with regard to hazard related to the composition of the atmosphere can be reported, e.g. global warming; ozone depletion in the stratosphere; ozone formation in the troposphere; acidification.	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAir.Air.HazAssessConcl
PNEC value	PNEC value with unit.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAir.Air.HazAssessConclVal
Explanation for hazard conclusion	Provide an explanation on the hazard conclusion chosen.	Rich text area	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForAir.Air.Justification
Hazard for terrestrial organisms		Header 1	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForTerrestrialOrganisms
Soil		Header 2	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForTerrestrialOrganisms.Soil
Hazard assessment conclusion	Enter a PNEC value if possible (most common situation) If no PNEC is reported, a standard justification can be selected from the picklist: - "no or insufficient data available at present" may be chosen for instance if no data are available on soil organisms and a hazard conclusion cannot be derived from the data available for aquatic organisms. - "no exposure of soil expected" may be chosen for instance when direct and	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForTerrestrialOrganisms.Soil.HazAssessConcl

	indirect exposure of soil is unlikely because no direct or indirect release to soil (e.g. via application of sewage treatment plant sludge) for all the uses of the substance. Such condition of use will have to be reported in all the exposure scenarios. - "no data available: testing technically not feasible" may be chosen if it is technically not possible to test the substance as a consequence of its properties: e.g. if it is very volatile, highly reactive or unstable or when mixing of the substance with water may cause danger of fire or explosion. - "no hazard identified" may be chosen if no adverse effects have been identified up to the limit test concentrations recommended for the reported experimental studies or if no hazard have been identified for aquatic organisms and, based on the properties of the substance it can be justified that no hazard is expected on soil organisms. In addition to those standard statements, a more detailed explanation on the reasons why no PNEC is provided should be reported in the "Explanation on the hazard conclusion" field.		
PNEC value	PNEC value with unit.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForTerrestrialOrganisms.Soil.HazAssessConclVal
Assessment factor	Specify the assessment factor used for deriving the PNEC (only whole number allowed) This field does not need to be filled –in if the equilibrium partitioning method has been used. If a non-default assessment factor is used, a justification should be provided in the "Explanations on the hazard conclusion" field.	Decimal	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForTerrestrialOrganisms.Soil.AssessmentFactor
Extrapolation method	Select from the picklist the extrapolation method used for deriving the PNEC. The assessment factor method is	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForTerrestrial

	applicable if results from tests with terrestrial organisms are available. The species sensitivity distribution method can potentially be applied only if at least 10 long-term data (and preferably more than 15) are available for different species covering at least 8 taxonomic groups. In the absence of any ecotoxicity data for terrestrial organisms, the PNEC may be calculated from data on pelagic organisms using the equilibrium partitioning method (EPM).		Organisms.Soil.ExtrapolationMethod
Explanation for hazard conclusion	When a PNEC is derived, • if it is derived using assessment factors, specify the data which have been used for its derivation, e.g. justify the selection of data amongst the different taxonomic groups and justify the assessment factor used, when needed. • When the statistical extrapolation method is used, report information on the data used (including a description of the representativeness of the different taxonomic groups) and the distribution model used (including information on goodness of fit). When the partitioning coefficient method is applied provide details on the model applied and input parameters. When no PNEC is derived, provide an explanation on the hazard conclusion chosen. Provide any additional information related to the hazard conclusion.	Rich text area	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForTerrestrialOrganisms.Soil.Justification
Hazard for predators		Header 1	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForPredators
Secondary poisoning		Header 2	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForPredators.SecondaryPoisoning
Hazard assessment conclusion	Enter a PNEC value if possible. If no PNEC is reported, a standard justification can be selected from the picklist: - "no potential for bioaccumulation" may be chosen for instance for substances with Kow<3 and if there is no other	Closed list	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForPredators.SecondaryPoisoning.HazAssessConcl

	evidence of accumulation potential - "no potential to cause toxic effects if accumulated (in higher organisms) via the food chain" may be chosen if the substance is not classified as H360, H361, H362, H372 or H373 on the basis of mammalian toxicity data - "no or insufficient data available at present" may be chosen for instance if the relevant toxicological data are not yet available - "no data available: testing technically not feasible" may be chosen if it is technically not possible to test the substance as a consequence of its properties: e.g. if it is very volatile, highly reactive or unstable substances, or when mixing of the substance with water may cause danger of fire or explosion.		
PNEC value	PNEC value with unit.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForPredators.SecondaryPoisoning.HazAssessConclVal
Assessment factor	Specify the assessment factor used for deriving the PNEC (only whole number allowed). If a non-default assessment factor is used, a justification should be provided in the "Explanations on the hazard conclusion" field.	Decimal	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForPredators.SecondaryPoisoning.AssessmentFactor
Explanation for hazard conclusion	Describe the rationale for the method applied. Specify the data which have been used for the derivation of the PNEC, e.g. justify the selection of data and justify the assessment factor used. Describe the different steps used for the PNEC derivation, including any conversion from NOAELs (toxicity studies) to NOECs and all equations applied. When no PNEC is derived, provide an explanation on the hazard conclusion chosen. Provide any additional information related to the hazard conclusion.	Rich text area	ENDPOINT_SUMMARY.EcotoxicologicalInformation.HazardForPredators.SecondaryPoisoning.Justification
Additional	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.E

information			cotoxicologicalInformation.Discussion
Conclusion on classification		Header 1	ENDPOINT_SUMMARY.EcotoxicologicalInformation.ConclusionOnClassification
	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.EcotoxicologicalInformation.ConclusionOnClassification.JustificationEnv

10.1 Effects on birds

Effects on birds - 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, including:
- 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			
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 organis	Select the organism(s) for which the endpoint was derived.	Multi select	ENDPOINT_SUMMARY.ToxicityBirds_EU_P

ms (species)		open list with remarks	PP.KeyValueForCsa.ShortTermToxicity.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.ShortTermToxicity.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.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_PPP.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_PPP.KeyValueForCsa.ShortTermToxicity.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) also must be reported.	Range with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.ShortTermToxicity.EffectConcentration
Short-term toxicity to birds			
Long-term toxicity to birds			ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.LongTermToxicity
Study name / type	Select the study for which the endpoint was derived.	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.LongTermToxicity.Link
Test organisms (species	Select the organism(s) for which the endpoint was derived.	Multi select open list with	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.LongTermToxicity.Test

)		remarks	OrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.LongTermToxicity.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.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_PPP.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_PPP.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_PPP.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).	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.HigherTierTesting.field1350
Additional	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_P

information			PP.Discussion

Effects on birds - 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 (LD_{50}) of the active substance. The study shall provide, where possible, LD_{50} values. The lethal threshold dose, time courses of response and recovery, the LD_{10} and LD_{20} shall be reported together with the no observed effect level (NOEL) and gross pathological findings. Where LD_{10} and LD_{20} cannot be estimated, an explanation shall be provided. Study design shall be optimised for the achievement of an accurate LD_{50}.

A study shall be provided establishing the short-term dietary toxicity. LC_{50} 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. LC_{50} and NOEC values shall be converted to daily dietary dose (LD_{50}) 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 EC_{10} and EC_{20} 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			
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	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods

	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		
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 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 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.Ma

			terialsAndMethods.Test Organisms
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.Test Organisms.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.Test Organisms.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
Nominal and measured doses /	List nominal and, if available, measured dose levels or test concentrations (with	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Stud

concentrations	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. For micro-organisms, average achieved dose in colony forming units (cfu) also must be reported.		yDesign.NominalAndMeasuredDosesConcentrations
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.ToxicityToBirds.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions
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 the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Examinations.DetailsOnReproductiveParameters
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	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.AnyO

methods incl. tables			therInformationOnMaterialsAndMethodsInclTables
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 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 include further details in the supplementary remarks field, e.g.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.BasisForEffect

	'related to number of eggs or young surviving'.		
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.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 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_RECORD.ToxicityToBirds.ResultsAndDiscussion.MortalityAndSubLethalEffects
Effects on reproduction	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	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectsOnReproduction

	in the sequence in which you refer to them in the text (e.g. '... see Table 1'). 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
EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438. https://www.efsa.europa.eu/en/efsajournal/pub/1438 10.2903/j.efsa.2009.1438

10.2 Effects on aquatic organisms

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:

Toxicity endpoints (such as LC50, EC10, EC20, EC50 and NOEC) shall be calculated on the basis of nominal or mean/initial measured concentrations.

Information on toxicity, infectiveness and pathogenicity to aquatic organisms must be reported

ENDPOINT_SUMMARY.AquaticToxicity			
Name	**Instructions**	**Data Type**	**Field path**
Administrative data	Administrative data summary – common block Conclude on the effects on aquatic organisms	Header 1	ENDPOINT_SUMMARY.AquaticToxicity.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AquaticToxicity.Discussion

Links to support materials
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, noted 15 January 2015) https://www.efsa.europa.eu/en/efsajournal/pub/3290 10.2903/j.efsa.2013.3290

OECD (2018). Guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals. OECD Series on Testing and Assessment No. 23 (Second edition) http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2000)6/REV1&docLanguage=En

10.2.1 Short-term toxicity to fish

Short-term 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			
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.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 assessed (EC50, LC50 or NOEC).	Closed list	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwaterFish.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	Half-bounded with closed list	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.Sh

	range, use both numeric fields together with the appropriate qualifier(s), if applicable. In mg or µg a.s./L	(Decimal)	ortTermToxicityFreshwaterFish.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.ShortTermToxicityFreshwaterFish.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
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

Short-term toxicity to fish - Endpoint study record

Purpose
A study shall be provided on the acute toxicity to fish (LC_{50}) and details of observed effects. Information on toxicity, infectiveness and pathogenicity to fish must be reported

ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.AdministrativeData
Data	Data source (Literature Reference) – common block	Heade	ENDPOINT_STUDY_REC

source		r 1	ORD.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
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	Report the relevant effect levels (e.g. EC50, LC50 and/or		ENDPOINT_STUDY_REC

concentrations	other). Repeat this block of fields for entering more than one effect level if necessary.		ORD.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.	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 the supplementary remarks field.	Open list with remar	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.EffectConcentratio

	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.	ks	ns.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.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
Any other information on on		Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.AnyOtherInformati

results incl. tables			onOnResultsInclTables
Sublethal observations / clinical signs	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. Optionally include clinical signs, using predefined (or other) table as proposed in TG 203, Annex 4. Percentages of test animals that showed symptomology. 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.	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

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)

ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP			
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.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 '<'	Range with closed	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.KeyValueForChemicalSafetyAsse

	or '<='. For a range use both numeric fields together with the appropriate qualifier(s), if applicable.	list (Decimal)	ssment.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			
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

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			
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 OCSPP 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.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	Text template	ENDPOINT_STUDY_RECORD.LongTermToxToFish.MaterialsAndMethods.TestOrganisms.DetailsOnTestOrganisms

	are requested by the respective regulatory programme.		
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.) 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_RECORD.LongTermToxToFish.ResultsAndDiscussion
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 Short-term toxicity to aquatic invertebrates

Short-term 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			
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
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	Half-bounded with closed list (Decimal)	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueC

	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		sa.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 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

Short-term 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 (EC_{50}) 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			
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.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: OECD Test Guideline 202: *Daphnia sp.* Acute Immobilisation Test US EPA OCSPP 850.1035 Mysid Acute Toxicity Test OECD Test Guideline 235: *Chironomus sp.*, 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.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.TestMaterials.TestMaterialInformation
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.TestConditions

Any other information 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.	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
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.	Check box	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.Nomin

			alMeasured
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: - 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
Effect concentrations			
Details on results	For micro-organisms, information on toxicity, infectiveness and pathogenicity to freshwater invertebrates 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	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ResultsAndDiscussion.ResultsDetails

	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.		
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.ShortTermToxicityToAquaInv.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.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.OveralRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ApplicantSummaryAndConclusion

10.2.4 Long-term and chronic toxicity to aquatic invertebrates

Long-term and chronic toxicity to aquatic invertebrates - 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, e.g.:
- Group: Specify Invertebrate species;
- Time scale;
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects).

ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_ [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
Parent / metabolite	Indicate whether the endpoint is for the active substance or a	Closed list	ENDPOINT_SUMMARY.LongTermToxicityToAqua

	metabolite		ticInvertebrates_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 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_PP

			P.HigherTierTesting.field 1350
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

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.

ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv			
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: *Daphnia magna* 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	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.MaterialsAndMethods

	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		
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
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.AnyOtherInformationOnMaterialsAndMethodsInclTables
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
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; - 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.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	For microorganisms:Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported. 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. 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.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
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 algal growth

Effects on algal 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			
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		Header 1	ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP.KeyValu

safety assessment			eCsa
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 = 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

Effects on algal 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			
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
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
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion
Effect	Report the relevant effect levels (e.g. EC50, LC50 and/or		ENDPOINT_STUDY_R

concentrations	other). Repeat this block of fields for entering more than one effect level if necessary.		ECORD.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.	Check box	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 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	Select effect parameter such as inhibition of respiratory	Open	ENDPOINT_STUDY_R

effect	rate or growth inhibition, which the effect concentration relates to. As appropriate include further details in the supplementary remarks field.	list with remarks	ECORD.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 field 'Attached background material'. Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.ResultsDetails
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

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			
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,	Header 1	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyInformation

	-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.		
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 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	ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP.KeyValueCsa.ToxAquaticPlants.EffectConcentration

		(Decimal)	
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_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

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.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 221: *Lemna sp.* Growth Inhibition Test ASTM E1913-04: Standard Guide for Conducting Static, Axenic, 14-Day Phytotoxicity Tests in Test Tubes with the Submersed Aquatic Macrophyte, *Myriophyllum sibiricum Komarov* OECD Test Guideline 238: Sediment-Free *Myriophyllum Spicatum* Toxicity Test OECD Test Guideline 239: Water-Sediment *Myriophyllum Spicatum* 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.MaterialsAndMethods.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.Stu

			dyDesign
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
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 (Deci	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.EffectConc

		mal)	
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 with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.BasisForEffectMulti
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.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on	Any abnormal adverse or beneficial effects in	Text	ENDPOINT_STUDY

results	treatment and/or control groups, including dates and times the effects were observed, 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 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').	template	_RECORD.ToxicityToAquaticPlant.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.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

10.3 Effect on arthropods including bees

Effect on arthropods including bees - 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 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
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.Subst

			ance
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
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	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.AnimalGroup

	non-target terrestrial arthropods).		
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 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	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueForCsa.LongTermToxTerrestrialArthropods.EffectConcentration

	Also, for micro-organisms, average achieved dose in colony forming units (cfu) must be reported.		
Long-term toxicity to terrestrial/soil arthropods			
Higher tier testing for safety assessment	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa). Is there potential for accumulative toxicity	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
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

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 LD_{50} 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 LD_{50} 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 EC_{10}, EC_{20}, EC_{50} together with the NOEC. Where the chronic oral EC_{10}, EC_{20}, EC_{50} 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 EC_{10}, EC_{20} and EC_{50} for adult bees, where possible, and larvae together with the NOEC. Where EC_{10}, EC_{20}, EC_{50} 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			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.AdministrativeData
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 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	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods
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.MaterialsA

			ndMethods.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. 'Hymenoptera (honeybees)' for honeybees or 'Collembola (soil-dwelling springtail)' for a test with Folsomia candida. Helpful for searching purposes.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.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.AnyOtherInf

			ormationOnMaterialsAndMethodsInclTables
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.ResultsAndDiscussion.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 weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.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.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 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.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	For microorganisms indicate that information on toxicity, infectiveness and pathogenicity to bees and	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAnd

	arthropods other than bees must be 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)). 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. 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 characterisation (to guarantee the proper exposure). 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). 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). 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		Discussion.ResultsDetails

	to your needs. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Ability to record multiple endpoint values (we can have different species, populations, communities etc.) 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 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.		
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.ToxicityToTerrestrialArthropods.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.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.Statistics
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.AnyOtherInfo

			rmationOnResultsInclTables
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 earthworms

Effects on earthworms - Endpoint summary

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 species;
- Route/time-scale
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects);
- Test type (laboratory/others);
- Dose (kg /ha).

Information on toxicity, infectiveness and pathogenicity to earthworms must be reported.

ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP			
Name	**Instructions**	**Data type**	**Field path**
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 *Eisenia fetida* (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 macroorga	Short term (acute) studies to soil macroorganisms are no longer required.		ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.ShortTermToxicitySoilOrganis

nisms except arthropods			ms
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
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 field	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.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 refere	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_E

		nce field	U_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 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.	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.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

Effects on earthworms - 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 EC_{10}, EC_{20} 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			
Name	**Instructions**	**Data type**	**Field path**
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 (*Eisenia fetida/Eisenia andrei*) 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.ToxicityToSoilMacroorganismsExceptArthro

			pods.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
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	Any other information on materials and methods	Header	ENDPOINT_STUDY_REC

information on materials and methods incl. tables	incl. tables - (H2) – common block	2	ORD.ToxicityToSoilMacroorganismsExceptArthropods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.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.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.	Indicate whether the concentration is based on the	Open	ENDPOINT_STUDY_REC

based on	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.	list with remarks	ORD.ToxicityToSoilMacroorganismsExceptArthropods.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.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'.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.ResultsDetails

	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').		
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.ToxicityToSoilMacroorganismsExceptArthropods.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.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

10.5 Effects on soil microorganisms

Effects on soil microorganisms - 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

ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP			
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)). 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
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

Effects on soil microorganisms - 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			
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.DataS

			ource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.DataSource.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.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.TestMaterials.TestMaterialInformation
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.TestOrganisms
Test organisms (inoculum)	Select 'soil' if soil samples were used as inoculum. Otherwise select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.TestOrganisms.TestOrganismsInoculum
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.StudyDesign
Test conditions	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.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_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.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_RECORD.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.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value and unit .	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.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_RECORD.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_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.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.Nomin

			alMeasured
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: - 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.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	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. 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	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.ResultsDetails

	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. 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.OveralllRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ApplicantSummaryAndConclusion

10.6 Additional studies

Additional studies - 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

ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants.KeyValueForChemicalSafetyAssessment
Short-term EC50 or LC50 for terrestrial plants		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants.KeyValueForChemicalSafetyAssessment.ShortTermEc50OrLc50ForTerrestrialPlants
Long-term EC10, LC10 or NOEC for terrestrial plants		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants.KeyValueForChemicalSafetyAssessment.LongTermEc10Lc10OrNoecForTerrestrialPlants
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants.Discussion

Additional studies - Endpoint study record

Purpose
A test shall provide the ER_{50} 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			
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.ToxicityToTer

			restrialPlants.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.TestOrganisms.TestOrganisms
Species	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.MaterialsAndMethods.TestOrganisms.TestOrganisms.Species
Plant	Select from drop-down list.	Open	ENDPOINT_STUDY_R

group		list	ECORD.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.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.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.KeyResult
Species	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsA

			ndDiscussion.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 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	Open list with remar	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectCo

	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'.	ks (2000)	ncentrations.Remarks OnResults
Effect concentr ations			
Details on results	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. 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 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'.	Text templ ate	ENDPOINT_STUDY_R ECORD.ToxicityToTer restrialPlants.ResultsA ndDiscussion.Results Details
Results with reference substanc e (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 templ ate	ENDPOINT_STUDY_R ECORD.ToxicityToTer restrialPlants.ResultsA ndDiscussion.Results RefSubstance
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_R ECORD.ToxicityToTer restrialPlants.ResultsA ndDiscussion.Statistic s
Any other	Any other information on results incl. tables Block	Heade	ENDPOINT_STUDY_R

information on results incl. tables		r 2	ECORD.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

11. 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			
Name	**Instructions**	**Data type**	**Field path**
General information	See administrative data	Header 1	FLEXIBLE_RECORD.ChangeLog.GeneralInformation
	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 authorisations. 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			

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. 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			
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.ReportsAdministrativ

			eInfo
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	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	Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS

	'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.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

EU PPP Microorganisms - active substance information

1 Identity of the microorganism and applicant

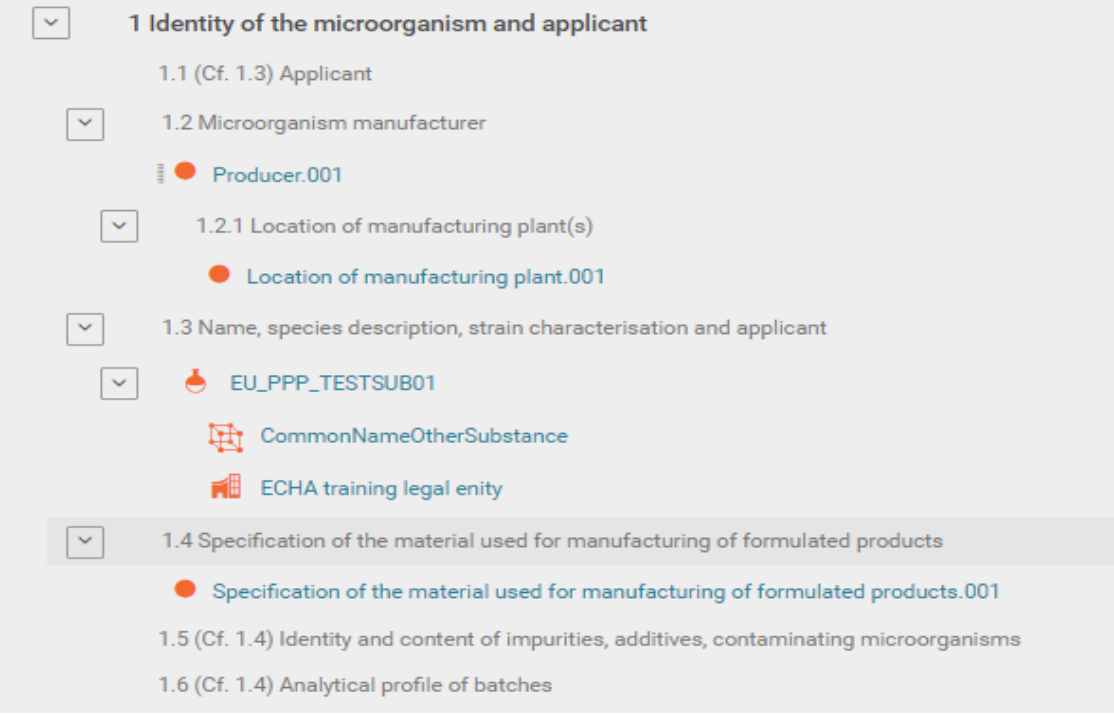
The following documents are located under section 1 "Identity of the microorganism and applicant":

1.2 Microorganism manufacturer: Suppliers – Flexible record

1.2.1 Location of manufacturing plant(s): Sites – Flexible record

1.3 Name, species description, strain characterisation and applicant – Substance

1.4 Specification of the material used for manufacturing of formulated products– Flexible record



1.2 Microorganism manufacturer

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			
Name	Instructions	IUCLID6 DataType	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 linked to the Substance or Mixture/Product dataset. To complete the information of this newly created Legal entity, click the Goto 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 .	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-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	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.NonEUManufacturerAssignment

	in the Properties window.		
Other importers	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.		FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries
Name	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. 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. 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 .	Entity reference field	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.ImporterEntries.LegalEntity
Agreement	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.	Single file attachment	FLEXIBLE_RECORD.Suppliers.OnlyRepresentationInfo.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			
Name	Instructions	Data Type	Field Path
	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. 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. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.Sites.DataProtection
Site	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. 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 . Caution 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.	Entity reference field	FLEXIBLE_RECORD.Sites.ReferenceSite
Remark	A remark field to enter additional information on the Site.	Text area	FLEXIBLE_RECORD.Sites.Remarks
Manufacture / own use(s)		Header 1	FLEXIBLE_RECORD.Sites.Manufacture
Related	Click the Linkbutton to select the relates	Endpoint	FLEXIBLE_RECORD.Site

manufacture / own use	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.	reference list	s.Manufacture.RelatedManufacture
Related mixture/product		Header 1	FLEXIBLE_RECORD.Sites.RelatedMixtureProduct
Specify to which mixture/product(s) it applies:		Endpoint reference list	FLEXIBLE_RECORD.Sites.RelatedMixtureProduct.SpecifyToWhichMixtureProductSItApplies

1.3 Name, species description, strain characterisation 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 section on "Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants"	Confidentiality	SUBSTANCE.OtherNames.DataProtection
Identifier		Open list	SUBSTANCE.OtherNames.NameType
Identity		Multi-line text	SUBSTANCE.OtherNames.Name
Country		Multi select	SUBSTANCE.OtherNames.Country

		open list	
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			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	Entity reference field	SUBSTANCE.ReferenceSubstance.ReferenceSubstance
Type of substance		Header 1	SUBSTANCE.TypeOfSubstance
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	Check 'Manufacturer' to indicate the applicant is the	Header	SUBSTANCE.RoleInS

supply chain	Producer of the active substance	1	upplyChain
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 (including contact entity)
ISO/TC 81

1.4 Specification of the material used for manufacturing of formulated products

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.

FLEXIBLE_RECORD.SubstanceComposition v.7.4 (Final)			
Name	**Instructions**	**Data**	**Field path**

		type	
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 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.	Open list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.StateForm
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.Attache

			dDocument
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. 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)'.	Endpoint reference list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.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.SubstanceComposition.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	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	Range	FLEXIBLE_RECORD.SubstanceComp

	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 '<=‘.	with open list (Decimal)	osition.Constituents.Constituents.Concentration
Remarks	Provide additional information about the constituent, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.Remarks
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.	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	Range with open	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.Concentr

	qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	list (Decimal)	ation
Remarks	Provide additional information about the impurity, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.Remarks
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.	Half-bounded with open list	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.ProportionTypical

		(Decimal)	
Concentration range	Indicate the concentration range of the additive 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.Additives.Additives.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.RelevantForClassificationLabeling
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

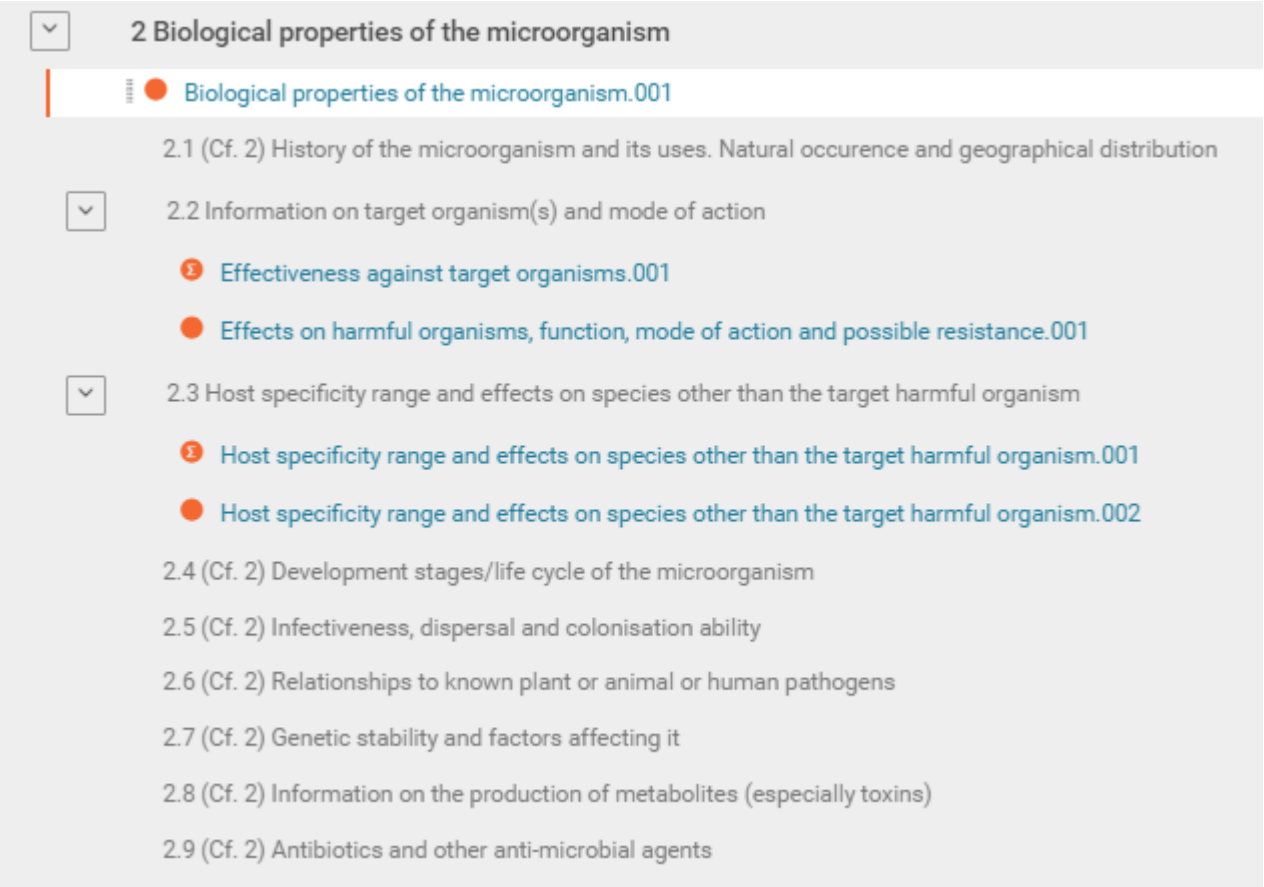
2 Biological properties of the microorganism

The following documents are located under section 2 "Biological properties of the microorganism":

2 Biological properties of the microorganism – Flexible record

2.2 Information on target organism(s) and mode of action: Effectiveness against target organisms Endpoint summary / Effectiveness against target organisms and intended uses - general information – Endpoint study record.

2.3 Host specificity range and effects on species other than the target harmful organism: Toxicity to other above-ground organisms Endpoint summary / Endpoint study record



Biological properties of the microorganism - Flexible record

Purpose
Provide information on familiarity, interpreted as the availability of relevant knowledge of the microorganism; Historical background, Origin and natural occurrence, Development stages/life cycle of the microorganism, Infectiveness, dispersal and colonisation ability, Relationships to known plant or animal or human pathogens, Genetic stability and factors affecting it, Information on the production of metabolites (especially toxins), Antibiotics and other antimicrobial agents

Provide information on the normal methods and precautions to be followed in the handling, storage and transport of the microorganism. The studies, data and information submitted must demonstrate the suitability of measures proposed for use in emergency situations.

Important Note: For a technical reason, which will be resolved in the next version it is not possible to add references in this document. All supporting evidence must included as literature references and added in the 'Summary and Evaluation' section. Include the relevant citations in the sections below.

FLEXIBLE_RECORD.BioPropertiesMicro v.1.3			
Name	Instructions	Data type	Field path
Administrative data		Header 1	FLEXIBLE_RECORD.BioPropertiesMicro.AdministrativeDataSummary
	Set the confidentiality flag and regulatory purpose. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.BioPropertiesMicro.AdministrativeDataSummary.DataProtection
Biological properties of the microorganism		Header 1	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism
General information on the microorganism		Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.GeneralInformationOnTheMicroorganism
	Familiarity (availability of relevant knowledge) of the microorganism not covered by the sections below If the micro-organism is genetically modified, the type of modification should be provided.	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.GeneralInformationOnTheMicroorganism.field1536
Historical background		Header 3	FLEXIBLE_RECORD.BioPropertiesMicro.Biological

			PropertiesOfTheMicroorganism.GeneralInformationOnTheMicroorganism.HistoricalBackground
	Historical background of the wild type. Provide information at the most relevant taxonomic level (e.g. strain, species, genus), and justify the choice of the relevant taxonomic level.	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.GeneralInformationOnTheMicroorganism.HistoricalBackground.field7165
Historical uses		Header 3	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.GeneralInformationOnTheMicroorganism.HistoricalUses
	Historical uses (tests/research projects or commercial uses) of the microorganism. Include both plant protection and other uses (e.g. uses and/or assessments under other regulatory frameworks, bioremediation, uses in food and feed). Provide information at the most relevant taxonomic level (e.g. strain, species, genus), and according to the valid and accepted taxonomic criteria applicable at the time of the submission of the application. Justify the choice of the relevant taxonomic level.	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.GeneralInformationOnTheMicroorganism.HistoricalUses.field1752
Origin, natural occurrence and geographical distribution		Header 3	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.GeneralInformationOnTheMicroorganism.OriginNaturalOccurrenceAndGeographicalDistribution
	The geographical region and the place in the ecosystem (e.g. host plant, host animal, or soil from which the micro-organism was isolated) must be stated. The method of isolation of the microorganism shall be reported. The natural occurrence of the microorganism in the relevant	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.GeneralInformationOnTheMicroorganism.OriginNaturalOccurrenceAndGeographicalDistribution.field6386

	environment shall be given, if possible at strain level. In the case of a mutant, or a genetically modified microorganism, detailed information should be provided on its production and isolation and on the means by which it can be clearly distinguished from the parent wild strain.		
Development stages / life cycle of the microorganism		Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.DevelopmentStagesLifeCycleOfTheMicroorganism
	Information on the life cycle of the microorganism, described symbiosis, parasitism, competitors, predators, etc., including host organisms, as well as vectors for viruses, must be presented. The generation time and the type of reproduction of the microorganism must be stated. A description of all forms that may occur must be included. For bacteriophages, information on, if applicable, lysogenic and lytic properties must be provided. Information on the occurrence of resting stages and their survival time, their virulence and infection potential must be provided. The potential of the microorganism to produce metabolites, including toxins that are of concern for human health and/or the environment, in its different development stages after the release, must be indicated.	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.DevelopmentStagesLifeCycleOfTheMicroorganism.field6313
Relationships to known plant or animal or human pathogens		Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.RelationshipsToKnownPlantOrAnimalOr

			HumanPathogens
	- The possible existence of species of the genus of the active and/or, where relevant, contaminating microorganisms known to be pathogenic to humans, animals, plants or other non-target species and the type of disease caused. - Means to clearly distinguish the active microorganism from the pathogenic species.	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.RelationshipsToKnownPlantOrAnimalOrHumanPathogens.field7482
Genetic stability and factors affecting it		Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.GeneticStabilityAndFactorsAffectingIt
	Where appropriate, information on genetic stability (e.g. mutation rate of traits related to the mode of action or uptake of exogenous genetic material) under the environmental conditions of proposed use must be provided. Information must also be provided on the microorganism's capacity to transfer genetic material to other organisms as well as its capacity to being pathogenic for plants, animals or man. If the microorganism carries relevant additional genetic elements, the stability of the encoded traits shall be indicated. - Plasmids or other mobile genetic elements. - Measures taken to minimise genetic drift.	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.GeneticStabilityAndFactorsAffectingIt.field3673
Information on the production of metabolites (especially toxins)		Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.InformationOnTheProductionOfMetabolitesEspeciallyToxins
	If other strains belonging to the same microbial species as the strain subject to the application are known to produce metabolites (especially toxins) with unacceptable effects on human health	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.InformationOnTheProductionOfMetabolit

	and/or the environment during or after application, the nature and structure of this substance, its presence inside or outside the cell and its stability, its mode of action (including external and internal factors of the microorganism necessary to action) as well as its effect on humans, animals or other non-target species shall be provided. The conditions under which the microorganism produces the metabolite(s) (especially toxin(s)) must be described. Any available information on the mechanism by which the microorganisms regulate the production of the(se) metabolite(s) shall be provided. Any available information on the influence of the produced metabolites on the microorganism's mode of action shall be provided. Make reference to the Document J for the identity of the metabolite(s). For metabolites produced *in-situ* after application make reference to the relevant sections.		esEspeciallyToxins.field1601
Production and resistance to antibiotics and other antimicrobial agents		Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.ProductionAndResistanceToAntibioticsAndOtherAntimicrobialAgents
	Many microorganisms produce some antibiotic substances. Interference with the use of antibiotics in human or veterinary medicine must be avoided at any stage of the development of a microbial plant protection product. Information on the microorganism's resistance or sensitivity to antibiotics or	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.ProductionAndResistanceToAntibioticsAndOtherAntimicrobialAgents.field5725

	other antimicrobial agents must be provided, in particular the stability of the genes coding for antibiotic resistance, unless it can be justified that the micro-organism has no harmful effects on human or animal health, or that it cannot transfer its resistance to antibiotics or other antimicrobial agents. - Level of production of any known antibiotics used in human or veterinary medicine. - Information on resistance or sensitivity to antibiotics or other antimicrobial agents.		
Robustness to environmental factors		Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.RobustnessToEnvironmentalFactors
	The persistence of the microorganism and information on its life cycle under the typical environmental conditions of use must be indicated. In addition, any particular sensitivity of the microorganism to certain compartments of the environment (e.g. UV light, soil, water) must be stated. The environmental requirements (temperature, pH, humidity, nutrition requirements, etc.) for survival, reproduction, colonisation, damage (including human tissues) and effectiveness of the microorganism must be stated. The presence of specific virulence factors shall be indicated. The temperature range at which the microorganism grows must be determined, including minimum, maximum and optimum temperatures. This information is of particular value as a trigger for studies of effects on human	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.RobustnessToEnvironmentalFactors.field9770

	health (Section 5). The possible effect of factors such as temperature, UV light, pH, and the presence of certain substances on the stability of relevant toxins must also be stated.		
Further information on the microorganism		Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.FurtherInformationOnTheMicroorganism
	Any further relevant information.	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganism.FurtherInformationOnTheMicroorganism.field5857
Effectiveness against target organisms		Header 1	FLEXIBLE_RECORD.BioPropertiesMicro.EffectivenessAgainstTargetOrganisms
Infectiveness, dispersal and colonisation ability	Information on possible dispersal routes of the microorganism (via air as dust particles or aerosols, with host organisms as vectors, etc.), under typical environmental conditions relevant to the use, must be provided. Influence of typical conditions of use on survival, growth, colonisation, and infectiveness of the microorganism. Indicate the presence of specific virulence factors, if any.	Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.EffectivenessAgainstTargetOrganisms.InfectivenessDispersalAndColonisationAbility
		Text template	FLEXIBLE_RECORD.BioPropertiesMicro.EffectivenessAgainstTargetOrganisms.InfectivenessDispersalAndColonisationAbility.field9314
Methods to prevent loss of virulence of seed stock of the microorganism	Methods to prevent loss of virulence of starting cultures shall be provided. In addition, any method, if available, that could prevent the microorganism from losing its effects on the target species must be described.	Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.EffectivenessAgainstTargetOrganisms.MethodsToPreventLossOfVirulenceOfSeedStockOfTheMicroorganism

		Rich text area	FLEXIBLE_RECORD.BioPropertiesMicro.EffectivenessAgainstTargetOrganisms.MethodsToPreventLossOfVirulenceOfSeedStockOfTheMicroorganism.field8887
Measures necessary to protect humans, animals and the environment	Methods to dispose safely of the microorganism or, where necessary, to kill it prior to disposal, and methods to dispose of contaminated packaging and contaminated materials, must be fully described. Data must be provided for such methods to establish their effectiveness and safety. Information on procedures for rendering the microorganism harmless in the environment (e.g. water or soil) in case of an accident must be provided. A safety data sheet pursuant to Article 31 of Regulation (EC) No 1907/2006 must be provided for each microorganism this should be uploaded with literature reference and included in the 'Summary and Evaluation section.	Header 1	FLEXIBLE_RECORD.BioPropertiesMicro.MeasuresNecessaryToProtectHumansAnimalsAndTheEnvironment
Monitoring plan to be used for the active microorganism including handling, storage, transport and use		Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.MeasuresNecessaryToProtectHumansAnimalsAndTheEnvironment.MonitoringPlanToBeUsedForTheActiveMicroorganismIncludingHandlingStorageTransportAndUse
	Post-approval monitoring might be considered for all areas of risk assessment. This is particularly the case when (strains of) microorganisms that are non-indigenous to the intended area of application are considered for approval.	Rich text area	FLEXIBLE_RECORD.BioPropertiesMicro.MeasuresNecessaryToProtectHumansAnimalsAndTheEnvironment.MonitoringPlanToBeUsedForTheActiveMicroorganismIncludingHandlingStorageTransportAndUse.field1483
Classification & Labelling of the microorganism		Header 1	FLEXIBLE_RECORD.BioPropertiesMicro.ClassificationLabellingOfTheMicroorganism

Relevant risk group specified in Article 2 of Directive 2000/54/EC	Indicate group 1 to 4 according to Directive 2000/54/EC.	Header 2	FLEXIBLE_RECORD.BioPropertiesMicro.ClassificationLabellingOfTheMicroorganism.RelevantRiskGroupSpecifiedInArticle2OfDirective200054EC
		Closed list	FLEXIBLE_RECORD.BioPropertiesMicro.ClassificationLabellingOfTheMicroorganism.RelevantRiskGroupSpecifiedInArticle2OfDirective200054EC.field1556
Biological properties of the microorganism in the biocidal product		Header 1	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganismInTheBiocidalProduct
	Not relevant for pesticides.	Text template	FLEXIBLE_RECORD.BioPropertiesMicro.BiologicalPropertiesOfTheMicroorganismInTheBiocidalProduct.field6878

Links to support material:
Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)
http://data.europa.eu/eli/dir/2000/54/2020-06-24

GUIDANCE ON THE RISK ASSESSMENT OF METABOLITES PRODUCED BYMICROORGANISMS USED AS PLANT PROTECTION ACTIVE SUBSTANCES SANCO/2020/12258

2.2 Information on target organism(s) and mode of action

Effectiveness against target organisms – Endpoint summary

Purpose:
This document summarises 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_SUMMARY.EffectivenessAgainstTargetOrganism			
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

Effects on harmful organisms, function, mode of action and possible resistance – Endpoint study record

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			
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.	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.BackgroundInformation

	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 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. 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		ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms

	names in a row in the related text field.		
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 the type of coding system in parentheses.	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.ScientificName
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 protected / under study		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.ProductsOrganismsOrObjectsToBeProtectedUnderStudy
Organisms (to be protected)	Describe and specify the organism(s) or materials(s) / object(s) to be protected,	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgain

or treated materials	e.g. human, pets, farm animals, fur- and wool-bearing animals, drinking water, hard surface material , porous surface.		stTargetOrganisms.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 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.	Open list	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.ProductType
Field of use envisaged / User	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	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FieldOfUseEnvisagedUser
Information on application of biocidal product		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.Informa

			tionOnApplicationOfBiocidalProduct
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 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.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.EffectsOnTargetOrganisms

	For products, efficacy studies should be reported using the corresponding template 'Efficacy data'.		
Mode of action	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..	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ModeAction
Details on mode of action	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	Text template	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.DetailsOnModeOfAction
(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		Header 1	ENDPOINT_STUDY_REC

discussion			ORD.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

Link to support materials

EPPO (2017) EPPO Global Database https://www.eppo.int/RESOURCES/eppo_databases

EPPO standards https://www.eppo.int/RESOURCES/eppo_standards

2.3 Host specificity range and effects on species other than the target harmful organism

Toxicity to other above-ground organisms - 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 on range and effects on non-target species.

ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data summary – common block Description of key information: Conclude	Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms.Administr

	on the non-target species for which the microorganism is pathogenic and whether the organism is capable of colonizing or invading humans or animals.		ativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms.KeyValueForChemicalSafetyAssessment
Short-term EC50 or LC50 for mammals	If relevant provide the value for short term effects in mammals	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms.KeyValueForChemicalSafetyAssessment.ShortTermEc50OrLc50ForMammals
Long-term EC10, LC10 or NOEC for mammals	If relevant provide the value for long term effects in mammals	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms.KeyValueForChemicalSafetyAssessment.LongTermEc10Lc10OrNoecForMammals
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms.Discussion

Toxicity to other above-ground organisms - Endpoint study record

Purpose:
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.

ENDPOINT_STUDY_RECORD.ToxicityToOtherAboveGroundOrganisms			
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
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

3 Further information on the microorganism

The following documents are located under section 3 "Further information on the microorganism":

3.4 Method of production and quality control – Flexible record

3.7 Recommended methods and precautions concerning handling, storage, transport or fire – Flexible record

3 Further information on the microorganism

3.1 (Cf. 2.2) Function

3.2 (Cf. relevant product, section 3.1) Field of use envisaged

3.3 (Cf. 3.2) Crops or products protected or treated

3.4 Method of production and quality control

Method of production and quality control.001

3.5 (Cf. 2.2) Information on the occurrence or possible occurrence of the development of resistance of the target organism

3.6 (Cf. 3.4) Methods to prevent loss of virulence of seed stock of the microorganism

3.7 Recommended methods and precautions concerning handling, storage, transport or fire

Recommended methods and precautions concerning handling, storage, transport or fire.001

3.8 (Cf. 3.7) Procedures for destruction or decontamination

3.9 (Cf. 3.7) Measures in case of an accident

3.4 Method of production and quality control

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.

FLEXIBLE_RECORD.Manufacturer_EU_PPP			
Name	**Instructions**	**Type**	**Field Path**
Administrative data		Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary
	See Confidentiality of dossiers Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary.DataProtection
Related compositions	Link to one or more compositions of the substance can be made which will then dis-play the corresponding name(s). This	Endpoint reference list	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary.

	link enables to transparently identify which composition of the substance is relevant for which use during its life cycle (from manufacture to service life).		RelatedCompositions
Description of key information	Describe the manufacturing process e.g. chemical pathways involved. 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 production are not available, a justification shall be provided.	Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.KeyInformation
	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	Select one or more of the following grounds for confidentiality to justify the claim **Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of Regulation (EC) No 178/2002)** 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;	Multi select open list with remarks	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.GroundsForConfidentialFile

	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 **Article 63(2)(b) of Regulation (EC) No 1107/2009** 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 **Article 63(2)(c) of Regulation (EC) No 1107/2009** results of production batches of the active substance including impurities **Article 63(2)(d) of Regulation (EC) No 1107/2009** information on the complete composition of a plant protection product **Article 39e (2) of Regulation (EC) No 178/2002** except for personal data (names and addresses) of individuals involved in testing on vertebrate studies or in obtaining toxicological information		

Justification	Provide additional information to support the claim	Text area	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.Justification
Conditions	Select condition/s that apply to the confidentiality claim **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; **Potential harm**: 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 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. **Worthiness of legal protection**: the document, information or data for which confidentiality treatment is requested is eligible for legal protection in the form of the award of the confidentiality status. **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.	Multi select open list with remarks	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.Conditions

	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.		
Document J	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.	Single file attachment	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.DocumentJ
Sanitised Document J	If relevant, a sanitised version can be uploaded.	Single file attachment	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.SanitisedDocumentJ
Attached background material	Additional background material can be uploaded here, use remarks to indicate the contents of the uploaded files		FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedBackgroundMaterial
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)	A sanitised version of any submitted background material must be uploaded	Attachments list	FLEXIBLE_RECORD.Manufacturer_EU_PPP.Additi

documents for publication	here, these will be published		onalInformation.AttachedSanitisedDocsForPublication

3.7 Recommended methods and precautions concerning handling, storage, transport or fire

Purpose:
The risks likely to arise and the methods and procedures to minimize the hazards arising, shall be specified.
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

FLEXIBLE_RECORD.ProtectionMeasures			
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 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	Substance: The field is used to identify all methods and precautions concerning the storage of an active substance. 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.	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.RecommendedMethodsAndPrecautionsConcerningStorage
Recommended	Describe all methods and precautions	Text area	FLEXIBLE_RECORD.Prot

methods and precautions concerning handling and transport	concerning handling and transport. Detailed handling procedures for the storage, at both warehouse and user level of plant protection products must be provided 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)		ectionMeasures.MeasuresToProtect.RecommendedMethodsAndPrecautionsConcerningHandling
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 This could include containment of spillages, decontamination of areas, vehicles and buildings, disposal of damaged packaging, absorbents and other materials, protection of emergency	Text area	FLEXIBLE_RECORD.ProtectionMeasures.MeasuresToProtect.EmergencyMeasuresToProtectEnvironmentInCaseOfAccident

	workers and residents, including bystanders 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		
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 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	Text area	FLEXIBLE_RECORD.ProtectionMeasures.Possibili

	on the soil.		tyOfDestructionOrDecontamination.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 procedures for industry or professional users. 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 Procedures to preclude or minimise the generation of waste or leftovers shall be provided.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.PossibilityOfReuseOrRecycling
Neutralisation procedure and possibility of neutralisation of effects	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 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 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.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.PossibilityOfNeutralisationOfEffects

	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.		
Conditions for controlled discharge including leachate qualities on disposal	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. 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.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.ConditionsForControllerDischarge
Conditions for controlled incineration	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) 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. 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.	Text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.ConditionsForControllerIncineration
Instructions for safe disposal of the product and its packaging for different groups of users	Not relevant for pesticides	Rich text area	FLEXIBLE_RECORD.ProtectionMeasures.ProceduresForWasteManagement.InstructionsForSafeDisposal

(relevant for biocidal products only)			
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 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. 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 Safety datasheets in the form of literature references can be added as references in this field	Literature reference list	FLEXIBLE_RECORD.ProtectionMeasures.AdditionalInformation.Reference

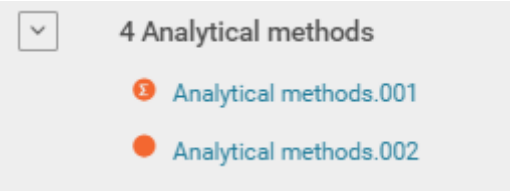
Links to support material:
Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) http://data.europa.eu/eli/dir/2010/75/2011-01-06

4. Analytical methods

The following documents are located under section 4 "Analytical methods":

Endpoint summary

Endpoint study record



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)

ENDPOINT_SUMMARY.AnalyticalMethods			
Label	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block 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	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.AdministrativeDataSummary
Additional information	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.	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.Discussion

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&doclanguage=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

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.

ENDPOINT_STUDY_RECORD.AnalyticalMethods			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.DataSource
Reference	Literature reference	Literature	ENDPOINT_STUDY_RECORD.AnalyticalMethods.

		reference list	DataSource.Reference
Background		Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.Background
Background 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_RECORD.AnalyticalMethods.Background.BackgroundInformation
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_RECORD.AnalyticalMethods.MaterialsAndMethods
Matrix / medium	Indicate the medium for which the analytical method is described. In the supplementary remarks field, you can add explanations as appropriate. 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.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.MatrixMedium
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.

			MaterialsAndMethods.TestMaterials
Principles of analytical methods		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods
Instrument / detector	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'. 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.	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods.InstrumentDetector
Details on analytical 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.PrinciplesOfAnalyticalMethods.DetailsOnAnalyticalMethod
Enforcement method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable
Instrume	If no enforcement method is proposed or required,	Multi	ENDPOINT_STUDY_REC

nt / detector for enforcement method	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'.	select open list	ORD.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
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.') 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.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.RecoveryResults
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	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.CharacteristicsOfAnalyticalMethod

	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'. Note: Specific tables may be required.		
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 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.') 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.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.RecoveryResults
Characteristics of 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), 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	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.CharacteristicsOfEnforcementMethod

	specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product: .....'). 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'). Note: Specific tables may be required.		
Independent laboratory validation (if applicable)	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.	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation
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,	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.

attachments			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

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

5 Effects on human health

The following documents are located under section 5 "Effects on human health":

5 Toxicological reference values – Flexible record

5.1 Basic information – Endpoint summary

5.1.2 Medical surveillance on manufacturing plant personnel – Endpoint study record

5.1.3 Sensitisation/allergenicity observations, if appropriate – Endpoint study record

5.1.4 Direct observation, e.g. clinical cases – Endpoint study record

5.2 Basic studies

5.2.1 Skin sensitization: Sensitisation Endpoint summary / Skin sensitization Endpoint study record

5.2.2 Acute toxicity, pathogenicity, and infectiveness – Endpoint summary

5.2.2.1 Acute oral toxicity, pathogenicity and infectiveness – Endpoint study record

5.2.2.2 Acute inhalation toxicity, pathogenicity and infectiveness – Endpoint study record

5.2.2.3 Intraperitoneal/subcutaneous single dose: Specific investigations: other studies Endpoint summary / Endpoint study record

5.2.3 Genotoxicity testing – Endpoint summary

5.2.3.1 In vitro studies – Endpoint study record

5.2.5 Information on short-term toxicity and pathogenicity – Endpoint summary

5.2.5.1 Health effects after repeated inhalatory exposure – Endpoint study record

5.2.5.2 Health effects after repeated oral exposure – Endpoint study record

5.2.5.3 Health effects after repeated dermal exposure – Endpoint study record

5.4 In vivo studies in somatic cells – Endpoint study record

5.6 Other basic studies and additional toxicological information: Additional toxicological information Endpoint summary / Endpoint study record

It is important than when presenting the results in tabular format for mammalian toxicology studies the applicant follows the recommendations of the "IUCLID templates for PPP Risk Assessment - Template 5.1 - Template for presentation of results in tabular format for mammalian toxicology studies" [http://doi.org/10.5281/zenodo.4557274].

Toxicological reference values – Flexible record

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			
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
		Confidenti	FLEXIBLE_SUMMARY.To

		ality	xRefValues.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
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)	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.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.OverallUncertainty
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation. 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 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. 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. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.JustificationOverallUf

	by-case basis.		
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.HumanHealthHazardCharacteristics.AcceptableDailyIntake
Not allocated	Check the box if an ADI is not necessary for the application	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.NoAllocated
Justification	Justification for the non-derivation of an ADI	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.Justification
ADI	Report the ADI value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.Adi
Study retained	Type of study used to derive the ADI (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.ToxRefValues.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.ToxRefValues.HumanHealthHazardCharacteristics.

			AcceptableDailyIntake.RouteOfOriginalStudy
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). 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 AOEL derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. - 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 data if those have been used. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.OverallUncertainty

	by-case basis.		
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.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	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.

		with remarks	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)	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.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 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. - 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. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.JustificationOverallUf

	relevant be applied and justified on a case-by-case basis. Justification for the uncertainty factor applied considering intra/inter species extrapolation		
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	Select the box if an AAOEL is not necessary for the application. It should be ticked for each toxicological reference value.	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.NoAllocated
Justification	Justification for the non-derivation of an AAOEL	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.Justification
AAOEL	Report the AOEL and if they are available select the relevant units.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.Aaoel
Study retained	Type of study used to derive the AAOEL	Multi	FLEXIBLE_SUMMARY.To

	(species and duration)	select open list with remarks	xRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.StudyRetained
Route of original study	Route of exposure in the study used to derive the AAOEL	Closed list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.RouteOfOriginalStudy
Oral absorption value (%)	Oral absorption value derived from the toxicokinetic studies expressed as a percentage	Decimal	FLEXIBLE_SUMMARY.ToxRefValues.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.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.OverallUncertainty
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation. 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 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. - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.JustificationOverallUf

	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 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. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.		
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 the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.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

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

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-exp-levs-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 Basic information

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			
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	Provide additional information related to the potential effects on human health of the micro-organism, including consideration of its pathogenic potential, its ability to infect and its toxicological effects.	Header 1	ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans.Discussion

5.1.2 Medical surveillance on manufacturing plant personnel

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			
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.DataSource
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	Select the appropriate study type. Optionally, include details in the supplementary remarks field. Definitions: - 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.	Open list with remarks	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.StudyType

	- Other: any other type of study or information, e.g. self-reported symptoms.		
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.HealthSurveillanceData.MaterialsAndMethods.EndpointAddressed
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	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.AnyO

incl. tables			therInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.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

5.1.3 Sensitisation/allergenicity observations, if appropriate

Purpose:
Available information on the sensitisation and allergenic response of workers, including workers in manufacturing plants, agricultural and research workers and others exposed to the micro-organism must be provided, and include, where relevant, details of any incidences of hypersensitivity and chronic sensitisation. The information provided shall include details of frequency, level and duration of exposure, symptoms observed and other relevant clinical observation. Information shall be given about whether workers have been subjected to any allergy tests or interviewed about allergenic symptoms.

ENDPOINT_STUDY_RECORD.SensitisationData			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SensitisationData.AdministrativeData

Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SensitisationData.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.SensitisationData.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: 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). OECD 429 OECD 442A + 442B.	Header 1	ENDPOINT_STUDY_RECORD.SensitisationData.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SensitisationData.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.SensitisationData.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Method		Header 2	ENDPOINT_STUDY_RECORD.SensitisationData.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. If 'Other' is selected, please include additional details in the free text box.	Multi select open list	ENDPOINT_STUDY_RECORD.SensitisationData.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	Open list with remarks	ENDPOINT_STUDY_RECORD.SensitisationData.MaterialsAndMethods.Metho

	'no' is selected, give reasoning as appropriate in the supplementary remarks field.		d.EthicalApproval
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. Note: The description of the race of individuals should be in accordance with ethical and legal standards. Above all, race should be self-described by the individuals.	Text template	ENDPOINT_STUDY_RECORD.SensitisationData.MaterialsAndMethods.Method.Subjects
Clinical history	Describe the clinical history of 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_STUDY_RECORD.SensitisationData.MaterialsAndMethods.Method.ClinicalHistory
Controls	Indicate control or reference group or other comparison group and application of control/reference substances.	Multi-line text	ENDPOINT_STUDY_RECORD.SensitisationData.MaterialsAndMethods.Method.Controls
Route of administration	Indicate the route of administration.	Open list	ENDPOINT_STUDY_RECORD.SensitisationData.MaterialsAndMethods.Method.RouteOfAdministration
Details on study design	Describe the test design, i.e. type of test(s) used, method of application and the examinations performed. Select freetext template for the respective type of sensitisation investigated and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.SensitisationData.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.SensitisationData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SensitisationData.ResultsAndDiscussion
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.SensitisationData.ResultsAndDiscussion.RsExa

	Give number of (persons with) positive / negative / equivocal reactions /results vs. number of study population or volunteers or samples. Include corresponding data for control groups if any. As appropriate, include or attach table(s) of results. For case reports, briefly describe the results including the grading (e.g.: +/-, +, ++, +++) after different reading times.		minations
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SensitisationData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.SensitisationData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SensitisationData.ApplicantSummaryAndConclusion

5.1.4 Direct observation, e.g. clinical cases

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			
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

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.TestMaterialInformation

Method		Header 2	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.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.DirectObservationsClinicalCases.MaterialsAndMethods.Method.TypeOfPopulation
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_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.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_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.EthicalApproval
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_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.RouteOfExposure
Reason of exposure	Indicate the reason of exposure e.g. intentional or occupational unitentional.	Open list	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.ReasonOfExposure
Exposure assessmen	Indicate whether the exposure was measured or estimated.	Closed list with	ENDPOINT_STUDY_RECORD.

t		remarks	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.DirectObservationsClinicalCases.ResultsAndDiscussion
Clinical signs	Describe any relevant signs and symptoms observed.	Text area	ENDPOINT_STUDY_RECORD.DirectObservati

			onsClinicalCases.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.DirectObservationsClinicalCases.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ApplicantSummaryAndConclusion

5.2 Basic studies

5.2.1 Skin sensitization

Sensitisation - 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			
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: quality of the study (e.g. Klimisch score, duration of the study,	Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.LinkToRelevantStudyRecords

	whether or not the study is GLP.		
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" is chosen, a justification needs to be provided.	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.EndpointConclusion
Additional information	Provide additional information related to the endpoint, for example: - 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. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.AdditionalInformation
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	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueFor

	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.		ChemicalSafetyAssessment.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

Skin sensitisation - 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
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.SkinSensitisation.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guideline: Method B.42 Skin sensitisation: Local lymph node assay (Annex to Regulation (EC) No 440/2008). Sensitisation Assays Addressing the Key Event on Activation of the Dendritic Cells on the Adverse Outcome Pathways for Skin Sensitisation Method B.71 In Vitro Skin Sensitisation assays addressing the key event on activation of dendritic cells on the adverse outcome pathway (AOP) for Skin Sensitisation	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods
Justification for non-LLNA method	(not relevant for micro-organisms)	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.JustificationForNonLLNAMethod
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.TestMaterials.TestMaterialInformation
In vitro test system	To be completed if the selected endpoint is skin sensitization: in vitro	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTest

			System
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 micro-organism/chemical 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.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.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.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	To be completed if the selected endpoint is skin sensitization: in chemico	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	To be completed if the selected endpoint is skin	Header 2	ENDPOINT_STUDY_

system	sensitization: in vivo		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 available from picklist, select 'other' and specify. NOTE: Human data should be reported in an appropriate subsection of section 'Basic information', particularly subsection 'Sensitisation/allergenicity observations'. 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.	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
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	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	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.DetailsOnTestAnimalsAndEnvironmentalConditions

	in which the test system is alive/growing).		
Study design: in vivo (non-LLNA)	To be completed if the selected endpoint is skin sensitization: in vivo (non-LLNA)	Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA
Induction	Record the vehicle, test micro-organism/chemical 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
Route	Indicate the route of induction exposure.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.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_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.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_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.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-	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesign

	irritant, indicate in field 'Details on study design' the appropriate pre-treatment applied for causing local irritation.		InVivoNonLLNA.Induction.AdequacyOfInduction
Induction			
Challenge	Record the vehicle, test micro-organism 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.	Closed 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, 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 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 - Exposure period: - - Test groups: TS - Control group: TS - Site: L flank - Concentrations: 4 different - Evaluation (hr after challenge): 24, 48, 72	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.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.InVivoTest

			System.StudyDesign InVivoNonLLNA.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.InVivoTestSystem.StudyDesignInVivoNonLLNA.PositiveControlSubstances
Study design: in vivo (LLNA)	To be completed if the selected endpoint is skin sensitization: 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 micro-organism. 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 relevant for evaluating this study summary or that are requested by the respective regulatory programme. - 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	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.DetailsOnStudyDesign

	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). MAIN STUDY - 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).		
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	To be completed if the selected endpoint is skin sensitization: in vitro or 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". 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. Note that Classification (CLP regulation) does not apply to micro-organisms.		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
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	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDi

	values, if those can be calculated.		scussion.InVitroInChemico.Results.Parameter
Value	Indicate also the unit of measurement e.g. µM, mM, µg/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 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'. - 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)	To be completed if the selected endpoint is skin sensitization: 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. Copy this block of fields as appropriate. Present the scores from the challenge responses in a table.		ENDPOINT_STUDY_RECORD.SkinSensitisation.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
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	This field can be used for:	Open list	ENDPOINT_STUDY_

result	- 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:'	with remarks (2000)	RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.RemarksOnResults
Results			
In vivo (LLNA)	To be completed if the selected endpoint is skin sensitization: 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. (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". 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. Note that Classification (CLP regulation) does not apply to micro-organisms.		ENDPOINT_STUDY_RECORD.SkinSensitisation.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).	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Parameter

	Further details can be given in the supplementary remarks field.		
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-animal variability in both the test substance and control groups when using the individual animal approach.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.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	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.CellularProliferationDataObservations

	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.		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
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

5.2.2 Acute toxicity, pathogenicity, and infectiveness – 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			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key information: Provide a	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.AdministrativeDataSummary

	brief description of toxicity studies and effects.		
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 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.AcuteToxicityViaOralRoute.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. 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 are also considered during the assessment. Dose descriptor: LC50 should usually be chosen. However, if the acute toxicity was	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.EndpointConclusion

	established by determining the discriminating concentration, that should be chosen.		
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. 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.AcuteToxicityViaDermalRoute.EndpointConclusion
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

5.2.2.1 Acute oral toxicity, pathogenicity and infectivenes

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 assesment 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 only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008.

ENDPOINT_STUDY_RECORD.AcuteToxicityOral			
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	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.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestType

	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.		
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. 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.	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. 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 in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
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 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'.		ENDPOINT_STUDY_RECORD.AcuteToxicityOral.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.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	Open list	ENDPOINT_STUDY_RECORD.AcuteToxici

	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.	with remarks	tyOral.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.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.ResultsAndDis

			cussion.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.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
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ApplicantSummaryAndConclusion

5.2.2.2 Acute inhalation toxicity, pathogenicity and infectiveness

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 × 10–2 Pa at 20 °C;
- the active substance is a powder containing a significant proportion of particles of a diameter < 50 µm (> 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			
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 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.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMeth

			ods.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
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 veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.	Closed 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 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.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMeth

	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').		ods.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.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		Heade	ENDPOINT_STUDY_REC

and discussion		r 1	ORD.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.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.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 concentration was used, select 'discriminating conc.', i.e the dose causing evident toxicity but not mortality. 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. For micro-organisms (CFU/L air or some other units should be used) 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.AcuteToxicityInhalation.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 with open	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscuss

	range use both numeric fields together with the appropriate qualifier(s) if applicable.	list (Decimal)	ion.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.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if relevant 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.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.cl
Exp. duration	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.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.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	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhal

	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.	with remarks	ation.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
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	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummaryAndConclusion

conclusion			
Executive summary		Rich text area	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummaryAndConclusion.ExecutiveSummary

5.2.2.3 Intraperitoneal/subcutaneous single dose

Intraperitoneal/subcutaneous single dose - 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 related to the infectiveness of the intraperitoneal/subcutaneous test.

ENDPOINT_SUMMARY.SpecificInvestigationsOtherStudies			
Name	**Instructions**	**Data Type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.SpecificInvestigationsOtherStudies.AdministrativeDataSummary
		Rich text area	ENDPOINT_SUMMARY.SpecificInvestigationsOtherStudies.KeyInformation.KeyInformation
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.SpecificInvestigationsOtherStudies.Discussion

Intraperitoneal/subcutaneous single dose - Endpoint study record

Purpose:
The intraperitoneal/subcutaneous test is considered a highly sensitive assay to elicit in particular infectiveness. The intraperitoneal injection is always required for all micro-organisms, however, expert judgement may be exercised to evaluate whether subcutaneous injection is preferred instead of intraperitoneal injection if the maximum temperature for growth and multiplication is lower than 37 °C.

ENDPOINT_STUDY_RECORD.SpecificInvestigations			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SpecificInvestigat

			ions.AdministrativeData
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_STUDY_RECORD.SpecificInvestigations.AdministrativeData.DataProtection
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SpecificInvestigations.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.SpecificInvestigations.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guidelines: Microbial Pesticide Test Guidelines: OPPTS 885.3200 Acute Injection Toxicity/Pathogenicity is relevant for this endpoint Note: Acute intraperitoneal/subcutaneous study is always in vivo.	Header 1	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods
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.	Multi select open list	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.EndpointAddressed
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Test animals	Test animals (OHT: Repeated dose toxicity)	Header 2	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.TestAnimals
Species	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: Although species 'human' is provided in the picklist for specifying the source of in vitro test systems as applicable, human data should be reported in an appropriate subsection of section 'Basic information'.	Open list	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.SpecificInvestigat

		with remarks	ions.MaterialsAndMethods.TestAnimals.Strain
Sex	Select as appropriate.	Closed list	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.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. 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.SpecificInvestigations.MaterialsAndMethods.TestAnimals.OrganismDetails
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.SpecificInvestigations.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.SpecificInvestigations.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.SpecificInvestigations.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verificatio	Indicate whether the doses or concentrations were analytically verified.	Closed list	ENDPOINT_STUDY_RECORD.SpecificInvestigat

n of doses or concentrations		with remarks	ions.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. - 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.SpecificInvestigations.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '28 days' or '18 months'.	Multi-line text	ENDPOINT_STUDY_RECORD.SpecificInvestigations.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.SpecificInvestigations.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Post	Indicate observation period (in days, weeks, months)	Multi-	ENDPOINT_STUDY_RE

exposure period	after last exposure to the test material. Specify, if there are differences for treatment and recovery groups or other individual groups.	line text	CORD.SpecificInvestigations.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, CFU/kg bw/day if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.SpecificInvestigations.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 (controls), 5 (in dose groups)'.	Multi-line text	ENDPOINT_STUDY_RECORD.SpecificInvestigations.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.SpecificInvestigations.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include details on the study design as appropriate.	Text area	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

Examinations		Header 2	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.Examinations
Examinations	Include details on the examinations performed.	Text area	ENDPOINT_STUDY_RECORD.SpecificInvestigations.MaterialsAndMethods.Examinations.Examinations
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.SpecificInvestigations.MaterialsAndMethods.Examinations.PositiveControl
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block For microorganisms: 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_RECORD.SpecificInvestigations.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SpecificInvestigations.ResultsAndDiscussion
Details on results	For microorganisms report (i) Number of animals at the start of the test. (ii) Time of death of individual animals. (iii) Number of animals displaying other signs of toxicity and pathogenicity. (iv) Description of toxic and pathogenic effects. (v) Expression of the dose levels with the appropriate unit for the microorganism under consideration (vi) Body weights at different time points. (vii) Necropsy findings. (viii) Pathology findings. (ix) Micro-organism enumeration from tissues, organs, and body fluids (at different time points), and methods used, and sensitivities and limits of detection (to address infectivity and clearance estimate).	Text area	ENDPOINT_STUDY_RECORD.SpecificInvestigations.ResultsAndDiscussion.ResultsDetails
Any other information on results	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SpecificInvestigations.ResultsAndDiscussion.AnyOtherInformatio

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

5.2.3 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			
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.KeyValueF

			orChemicalSafetyAssessment.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: 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.	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro.LinkToRelevantStudyRecords
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.DescriptionOfKeyInf

			ormation
		Rich text area	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.DescriptionOfKeyInformation.KeyInfo
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. Available epidemiological data are preferred provided that they are reliable and relevant.	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.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. If the dossier contains a testing proposal for genetic toxicity in vivo, "No study available (further information	Closed list	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.EndpointConclusion.EndpointConclusion

	necessary)" should be chosen.		
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.MoAHumanRelevanceFramework
	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.GeneticToxicity.KeyValueForChemicalSafetyAssessment.MoAHumanRelevanceFramework.MoAHumanRelevanceFramework
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: - In vitro studies (state the available in vitro studies and the results), - In vivo studies (state the available in vivo studies and the results) Provide an statement on the photomutagenicity potential: e.g. -Not required -Unlikely to be photomutagenic Attached background material: Provide the original version of any document that contains confidential material.	Header 1	ENDPOINT_SUMMARY.GeneticToxicity.Discussion

	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]		
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.GeneticToxicity.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.GeneticToxicity.JustificationForClassificationOrNonClassification.Remarks

5.2.3.1 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			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.AdministrativeData
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 OECD 473 OECD 476	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods

	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			
Cytokinesis 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.	Closed 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 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.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Vehicle
Controls	Indicate whether vehicle, true negative and/or positive controls were tested. Repeat this block of fields as		ENDPOINT_STUDY_RECORD.GeneticToxicit

	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'.		yVitro.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 justification. Final concentration, conditions and durations of treatment and recovery periods. Note that the list of substances provided is not exhaustive.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.PositiveControlSubstance
Remarks	Enter any remarks related to the recorded controls as appropriate.	Text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.Remarks
Controls			
Details on test	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for	Text templ	ENDPOINT_STUDY_RECORD.GeneticToxicit

system and experimental conditions	evaluating this study summary or that are requested by the respective regulatory programme.	ate	yVitro.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 discussion		Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion
Test results	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.) 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		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs

	tabulated.		
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.	Closed list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.MetActIndicator
Genotoxicity	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'). Note: Specific tables may be required.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.Genotoxicity
Cytotoxicity / choice of top concentrations	Indicate whether cytotoxicity was observed. If yes, specify the respective test concentration(s) in the 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.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.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 rema	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.TrueNe

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

5.2.5 Information on short-term toxicity and pathogenicity – Endpoint summary

Purpose:
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:

- 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).

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.

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).

ENDPOINT_SUMMARY.RepeatedDoseToxicity			
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 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.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.ToxicEffectType
Repeated dose toxicity: via oral route - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRouteSystemicEffects
Link to relevant study records	Endpoint summary block for relevant study record Study name / type: The study giving rise to the highest concern should be chosen e.g.	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedD

	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		oseToxicityViaOralRoute SystemicEffects.LinkToRelevantStudyRecords
Endpoint conclusion	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). 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. Study duration: The duration of the selected robust study summary. Species: The species reported in the selected robust study summary should be chosen here. 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	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRoute SystemicEffects.EndpointConclusion

	concern should be selected, i.e. the system that is associated with the dose descriptor. 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.		
Repeated dose toxicity: inhalation - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects
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.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects.LinkToRelevantStudyRecords
Endpoint conclusion	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). 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	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects.EndpointConclusion

	selected robust study summary. Species: The species reported in the selected robust study summary should be chosen here. 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. 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.		
Repeated dose toxicity: inhalation - local effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects
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.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects.LinkToRelevantStudyRecords
Endpoint conclusion	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.	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects.EndpointConclusion

	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. Study duration: The duration of the selected robust study summary. Species: The species reported in the selected robust study summary should be chosen here. 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. 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.		
Repeated dose toxicity: dermal - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects
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.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects.LinkToRelevantStudyRecords
Endpoint	Endpoint conclusion block (Species version)	Header 3	ENDPOINT_SUMMARY.R

conclusion	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). 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. Species: The species reported in the selected robust study summary should be chosen here. 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. 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.		epeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects.EndpointConclusion

Repeated dose toxicity: dermal - local effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects
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.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.LinkToRelevantStudyRecords.Results
Endpoint conclusion	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). 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. Species: The species reported in the	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.EndpointConclusion

	selected robust study summary should be chosen here. 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. 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.		
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 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)	Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.Discussion
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

5.2.5.1 Health effects after repeated inhalatory exposure – 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			
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 Note that the OECD guidelines (and EC) are applicable to toxins if tested in isolation, while only OPPTS is applicable to the micro-organism.	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxici

			tyInhalation.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
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.MaterialsAnd

			Methods.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.	Closed 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
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		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrat

	to the relevant unit used for the effect levels may be required.		ions
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
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.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.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

	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.		
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.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_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
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_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.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_RECORD.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_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.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_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	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'.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	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).	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.TargetSystemOrganToxicity
Any	Any other information on results incl. tables Block	Head	ENDPOINT_STUDY_REC

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

5.2.5.2 Health effects after repeated oral exposure – Endpoint study record

Purpose:
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.

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.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.AdministrativeData
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.	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods

	Method B.27 Sub-chronic oral toxicity test. 28 d OECD 407 Method B.7 Repeated dose (28 d).		
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)	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 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.RepeatedDoseToxicityOral.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 verificati	Indicate whether the doses or concentrations were analytically verified.	Closed list with	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMeth

on of doses or concentrations		remarks	ods.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
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 meas	ENDPOINT_STUDY_RECORD.RepeatedDoseToxic

		ure with Open List (Decimal)	ityOral.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
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	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

	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.		
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' 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_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
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.Option

			alEndpointS
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
Results of examinations	Results of examinations BLOCK (OHT: Repeated dose toxicity: oral)	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels BLOCK (OHT 67-69, 72-74) 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'.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.EffectLevels

Target system / organ toxicity	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).	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 conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ApplicantSummaryAndConclusion

5.2.5.3 Health effects after repeated dermal exposure – 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			
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	Material and methods – common block Applicable test guideline:	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxici

methods	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.		tyDermal.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
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.	Closed list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of	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	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConc

doses or concentrations	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.		entrations
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.AdministrationExpo

			sure.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 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.RepeatedDoseToxicityDermal.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.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	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate	Text templ	ENDPOINT_STUDY_RECORD.RepeatedDoseToxici

examinations performed and frequency	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' 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.	ate	tyDermal.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
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.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.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_RECORD.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_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results		Head	ENDPOINT_STUDY_REC

and discussion		er 1	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. 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 an clearance estimate) should be determined and reported.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	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. 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'.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.EffectLevels
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.RepeatedDoseToxicityDermal.ResultsAndDiscussion.EffectLevels.Efflevel.RemarksOnResults
Target system / organ	Target system BLOCK (OHT RepDoseTox etc.) Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDisc

toxicity	are in a dose-response manner (monotonic or non-monotonic).		ussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.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

5.4 In vivo studies in somatic cells -Endpoint study record

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.

ENDPOINT_STUDY_RECORD.GeneticToxicityVivo			
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	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods

	OECD 488 Method B.39 Unscheduled DNA synthesis (UDS) - Test with mammalian liver cells in vivo In vivo Comet assay.		
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.Duration

			OfTreatmentExposure
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.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.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 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 information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

	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.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
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.	Check box	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.KeyResult
Sex	Select from drop-down list.	Closed 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 supplementary remarks field or representative table, e.g. predefined table or an excerpt from the study report.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.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'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.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.ResultsAndDiscussion.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.ResultsAndDiscussion.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.ResultsAndDiscussion.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.ResultsAndDiscussion.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). Note: Depending on the regulatory programme some form of a table may be mandatory.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.ResultsDetails
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

5.6 Other basic studies and additional toxicological information

Other basic studies and additional toxicological information - 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.

ENDPOINT_SUMMARY.AdditionalToxicologicalInformation			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide a brief description of additional toxicological studies and effects.	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: - 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	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.Discussion

	(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. If there is no additional information to be reported this field may be left empty. *See IUCLID templates for PPP Risk Assessment - Template 5.4 - Template summary table on the assessment of the toxicological profile of metabolites* [http://doi.org/10.5281/zenodo.4557353]"		

Other basic studies and additional toxicological information - 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			
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.DataSource

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. 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, hematoxicity, hepatotoxicity, mechanistic studies, methaemoglobinaemia, nephrotoxicity, phototoxicity, respiratory irritation, splenic toxicity, or toxicogenomics.	Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.TypeOfStudyInformation
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
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

6 Residues in or on treated articles, food and feed

The following documents are located under section 6 "Residues in or on treated articles, food and feed":

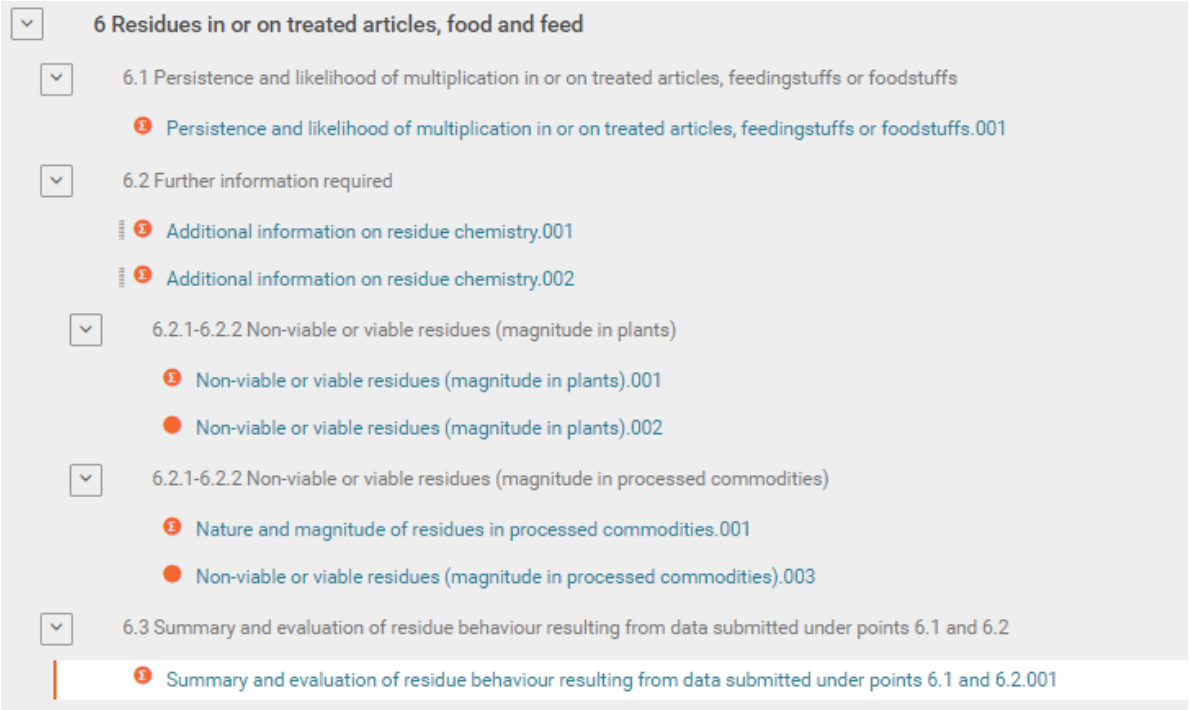
6.1 Persistence and likelihood of multiplication in or on treated articles, feedingstuffs or foodstuffs: Migration of residues into and their behaviour on food or feedingstuffs Endpoint summary / Endpoint study record

6.2 Further information required: Additional information on residue chemistry Endpoint summary / Endpoint study record

6.2.1-6.2.2 Non-viable or viable residues (magnitude in plants): Magnitude of residues in plants Endpoint summary / Residues in crops (field trials) and in rotational crops (limited field studies) Endpoint study record

6.2.1-6.2.2 Non-viable or viable residues (magnitude in processed commodities): Nature and magnitude of residues in processed commodities Endpoint summary / Magnitude of residues in processed commodities Endpoint study record

6.3 Summary and evaluation of residue behaviour resulting from data submitted under points 6.1 and 6.2 – Endpoint summary



6.1 Persistence and likelihood of multiplication in or on treated articles, feedingstuffs or foodstuffs

Persistence and likelihood of multiplication in or on treated articles, feedingstuffs or foodstuffs - Endpoint Summary

Purpose
Provide summary information on the persistence and likelihood of multiplication of viable and on the presence and/or production of non-viable residues in or on treated articles, feedingstuffs or foodstuffs following treatment under good agricultural conditions as relevant for the given context pursuant to the applicable regulatory framework.
In case that relevant information is provided in other sections of the dossier e.g. non-viable residues: metabolites or toxins for example under 'biological properties' and/or 'toxicology', please indicate this. Considering that the specific sections 6.1 to 6.3 allow to report all the data supporting the application, it is highlighted that all relevant additional data on the nature and magnitude of residues in food or feeding stuffs should be reported in the respective sections (6.2, 6.3) and not here to avoid duplication of reporting.

ENDPOINT_SUMMARY.MigrationOfResiduesIntoAndTheirBehaviourOnFoodOrFeedingstuffs			
Name	**Instructions**	**Data type**	**Field path**
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

Persistence and likelihood of multiplication in or on treated articles, feedingstuffs or foodstuffs - Endpoint study record

Purpose

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 context of the assessment such as representative use(s), intended use(s), authorised use(s), import tolerance(s) etc.

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. Moreover, the application shall state to which extent and on which basis it is considered that the micro-organism can (or cannot) multiply and/or persist in or on the plant or plant product or during processing of raw products.

The applicant is encouraged to provide stability data of the non-viable and/or viable residues as available by considering the 'Other factors affecting stability' section of the Product dataset.

ENDPOINT_STUDY_RECORD.MigrationOfResidues			
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.MigrationOfResidu

			es.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.MigrationOfResidues.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 non-viable and/or viable residues 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 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. For more detailed information or tables use	Open list with remarks	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.MigrationIntoFoodOrFeedingstuffs.Observation

	fields 'Details on results' or 'Any other information on results incl. tables', respectively. For microorganisms indicate whether the micro-organism and relevant secondary metabolites (especially toxins) were persistent in the raw agricultural commodity, foodstuff, feedingstuff etc.		
Transformation products	Please indicate available information, on any transformation products e.g. of metabolites. 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.MigrationOfResidues.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	Indicate, if available, the identity of the transformation products. 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.MigrationOfResidues.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.MigrationOfResidues.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.MigrationOfResidues.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Indication of organoleptic changes	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.	Closed list with remarks	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.IndicationOfOrganolepticChanges
Details on results	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	Text area	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ResultsAndDiscussion.DetailsOnResults

	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'). As appropriate also attach figures with kinetics of disappearance curves in field 'Illustration (picture/graph)' in 'Overall remarks, attachments'. Note: Specific tables may be required. Consult the programme-specific guidance thereof. For microorganisms provide information on observations related to viable and/or non-viable residues e.g. germination, multiplication, growth, metabolite production, metabolite persistence etc.'		
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 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	Header 1	ENDPOINT_STUDY_RECORD.MigrationOfResidues.ApplicantSummaryAndConclusion

6.2 Further information required

Additional information on residue chemistry - Endpoint summary

Purpose
Provide summary information concerning the non-viable and/or viable residues as available e.g. on raw agricultural commodity at harvest, feedingstuff" considering the information from the studies reported in section 6.2

ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Provide a brief description of additional study(ies) and of the key conclusions derived from this/these study(ies).	Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion

Additional information on residue chemistry - Endpoint study record

Purpose
The purpose of this section is reporting studies concerning the non-viable and/or viable residues in or on treated articles, feedingstuffs or foodstuffs following treatment with relevance for dietary consumer exposure.

Such studies may describe the nature and magnitude of non-viable and/or viable residues in raw and processed commodities or rotational crops or other as deemed relevant for the residue behaviour of micro-organisms.

Consumers may be exposed to micro-organisms (and viable or non viable residues) for a considerable time as a result of the consumption of treated food commodities;

Potential effects on the consumers must, therefore, be derived from chronic or semi-chronic studies, so that a toxicological end point, such as the ADI, which is performed in the toxicology section of the assessment. The residue section is assessing dietary consumer exposure to residues and needs the information to conclude whether there are any unacceptable risks resulting from dietary consumption of treated food produce as a consequence of non-viable or viable residues.

If toxicological reference values are not available, the provided information on the magnitude of relevant non-viable and/or viable residue may be sufficient to exclude any potential dietary risk for the consumer.

This document can also be used to report other residue studies submitted in the application where no other suitable document exists.

ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource
Materials and methods	Material and methods – common block 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.	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.StudyDesign
Details on study design	Describe the study design, e.g. what samples of representative food or feedingstuffs or their simulates were exposed to the substance and for how long. Provide sufficient details on the sampling and analytical methods used. Consult any programme-specific guidance. When summarising various studies, it may be appropriate to include a table in the rich text field 'Any other information on materials and methods incl. tables'.	Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.StudyDesign.FurtherDetailsOnStudyDesign
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.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion
Details on results	Provide detailed results of the additional information (other than reported under section 6.2.1. and 6.2.2.) available for non-viable and/or viable residue to characterise the residue behaviour ant its relevance for good agricultural conditions/uses. As appropriate include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. 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	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Not mandatory. Summary to be provided as part of Endpoint summary	Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicantSummaryAndConclusion.ExecutiveSummary

6.2.1-6.2.2 Non-viable or viable residues (magnitude in plants)

Non-viable or viable residues (magnitude in plants) - Endpoint summary

Purpose

To provide summary information on the magnitude of residues in plants following treatment under good agricultural conditions as relevant for the context. The provided information shall allow to conclude whether the magnitude of residues in plant (primary crops) was sufficiently elucidated in the context of the dossier.

ENDPOINT_SUMMARY.MagnitudeResiduesPlants			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation
	Please make a statement whether the magnitude of residues in plant 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. 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. 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.MagnitudeResiduesPlants.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.MagnitudeResiduesPlants.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. MagnitudeResiduesPlants.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. MagnitudeResiduesPlants.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 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.	Multi select open list	ENDPOINT_SUMMARY. MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.CommodityForMrl
Commodity(ies) used in the residue trials	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.	Multi select open list	ENDPOINT_SUMMARY. MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Commodity
Residue levels: RD RA	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 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. For micro-organisms it is to be noted that residue definitions are not applicable at present in the regulatory context. Nevertheless, in case of availability quantitative information on viable and/or non-viable residues can be reported.	Multi-line text	ENDPOINT_SUMMARY. MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResiduelevelsRiskAssessment
Residue levels: RD MO	If residue definition (RD) for risk assessment (RA) and RD for monitoring are different,	Multi-line text	ENDPOINT_SUMMARY. MagnitudeResiduesPlant

	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. For micro-organisms it is to be noted that for micro-organisms residue definitions for monitoring are not applicable at present. Nevertheless, in case of availability quantitative information on viable and/or non-viable residues can be reported.		s.KeyInformation.SummaryResiduesData.ResidueLevelsMonitoring
Mean conversion factor (CF)	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.	Decimal	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.MeanConversionFactor
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	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.MrlDerived
Remarks	Please insert here any other remarks, if	Text area	ENDPOINT_SUMMARY.

	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.		MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Remarks
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 OECD calculator Excel, available for single and multiple data sets here:	Attachments list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedSanitisedDocsForPublication

	https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm The uploaded file should not contain confidential material.		

Non-viable or viable residues (magnitude in plants) - Endpoint study record

Purpose

Purpose of document: Studies concerning the magnitude of viable and non-viable residues in plants following treatment under good agricultural conditions relevant for the representative use(s). Non viable: If relevant quantities of the micro-organism or of produced metabolites, especially toxins, have been found to be persistent in points 2.4 and 2.5, full experimental residue data as provided for in Section 6 of Part A of Annex to Commission Regulation (EU) No 283/2013 is required, if concentrations of the micro-organism and/or its toxins in or on the treated foodstuffs or feedingstuffs are expected to occur in concentrations higher than under natural conditions or in a different phenotypic state.

Particular attention shall be given as to whether (secondary) metabolites and/or toxins can be potentially formed by the microorganism following treatment and whether they are expected in relevant quantities in edible commodities.

Viable: If the information submitted in accordance with point 6.1 suggests persistence and/or multiplication of relevant amounts of the micro-organism in or on treated products, food or feed, possible effects on humans and/or animals must be investigated, unless it can be justified from Section 5, that the micro-organism and its metabolites and/or degradation products are not hazardous to humans in the concentrations and of the nature that could occur as a result of authorised use. In accordance with Regulation (EC) No 1107/2009, the conclusion concerning the difference between natural concentrations and an elevated concentration due to treatment with the micro-organism, is to be based on experimentally obtained data, and not on 'purely theoretical' extrapolations or calculations using models e.g. from anticipated application rates (viable counts applied when treatment is performed) in accordance with GAPs.

Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed (Commission Regulation (EU) No 283/2013).

ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	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
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.DataSource
Materials and methods	Material and methods – common block OPPTS 885.2500 Magnitude of Residues in Plants [EPA 712–C–96–307] is relevant for microorganisms	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.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.ResiduesInRotationalCrops.MaterialsAndMethods.ProductType
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.TestMaterials
Analytical methods		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods
Analytical method	This block of fields can be repeated to cover each analytical methods used to analyse samples. All combinations of: - analytical method - analysed matrix and - analysed substance should be defined to reuse them in block "Residue"		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 rest of this block is not required.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.MethodID
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.RelatedInformation
Details on		Text templ	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.Ma

analytical methods		ate	terialsAndMethods.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
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.Comb

			inationsOfSubstanceAndSamplePortion.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 agricultural practices on primary crops. It is to be noted that for micro-organisms supervised residue trials on primary crops are not required at present. Nevertheless, in case of availability information on residue trials performed and information obtained on viable and/or non-viable residues for given good agricultural practices can be reported.	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern
Trial ID no.	Insert the trial specific, unequivocal identification code	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialIdNo
Trial information	For chemicals: 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. Option 2: Report the detailed residue trial information directly in the Excel file Residues trial table (Template 6.3 (DOI to be created on Zenodo) (primary and rotational crops), to be attached in the field below "Attached background material". (See detailed instructions in "Attached background material") For option 2, there might be some information, which is relevant for the residue trial, but not captured in the Excel residue trial tables. This information can be reported in the field `Any other		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation

	information on materials and methods, incl.tables`. For micro-organisms: Please include any information which may be available		
Geographic location and soil characteristics		Header 3	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics
Test site type		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TestSiteType
Geographic location		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.GeographicLocation
Trial deviation		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TrialDeviation
Year		Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.Year
Country or territory		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.Country
Geographic region		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.GeographicRegion
State/Province		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.Ma

			terialsAndMethods.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.GeographicLocationAndSoilCharacteristics.TypeOfTrial
Crop grouping (primary)		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropGroupingPrimary
Crop group		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropGroup
Crop		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.Ma

			terialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.Crop
Crop code		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropCode
Crop variety		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropVariety
Replant no. (1, 2)		Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.ReplantNo
Date of planting		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfPlanting
Date of seeding		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfSeeding
Date of flowering (beginning)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfFloweringBeginning
Date of flowering (end)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfFloweringEnd
Date of harvest		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.Ma

(beginning)			terialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfHarvestBegin
Date of harvest (end)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.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.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot
Plot ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDesc

			ription.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.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application
Application			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application
Application no. (1, 2)		Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.ApplicationNo
Bare soil		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePa

			ttern.TrialInformation.PlotDescription.Plot.Application.Application.BareSoil
Growth stage code (BBCH) at application		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.GrowthStageCode
Growth stage description at application		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.GrowthStage
Date of application		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.DateOfApplication
Method of application		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.MethodOfApplication
Seeding rate		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.SeedingRate
Thousand grain weight		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.ThousandGrainWeight
Applied test material			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDesc

			ription.Plot.Application.Application.TestItem
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.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.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredient

			s.NameOfAI
Nominal a.i. content		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.NominalAIContent
Applied amount (actual)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AppliedAmountActual
Amount a.i./seed (actual)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AmountAISeedActual
Applied amount (cumulative nominal)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AppliedAmountCumulative
Adjuvant added		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.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
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		Text	ENDPOINT_STUDY_RECORD.

on analytical methodology for soil residues		template	ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil.DetailsOnAnalyticalMethodologyForSoilResidues
Plot			
Trial information			
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 can enter any information on materials and methods, for which no distinct field is 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.	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion
Storage stability of residues (Sample integrity)	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	Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.StorageStability

	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. For chemicals: Where samples were not analysed within 30 days, provide evidence showing that the storage did not affect the results of the study.		
Summary of residues	For chemicals: 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 (Template 6.3 (DOI to be created on Zenodo) (primary and rotational crops), to be attached in the field below "Attached background material". (See detailed instructions in "Attached background material") For micro-organisms: Please include any information which may be available	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
Sampling ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SamplingID
Sampling timing		Open list with rema	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.S

		rks	amplingAndResidues.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.SummaryOfRadioactiveResiduesInCrops.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.S

			amplingAndResidues.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.ResultsAndDiscussion.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		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryO

stability			fRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CorrectionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ReferencePortion
Residue level (measured)		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ResidueLevelMeasured
Calculated analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CalculatedAnalyteIdentity
Residue level (calculated)		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ResidueLevelCalculated
Residue level (calculated and correcte		Range with open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueL

d)		(Decimal)	evels.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	Overall remarks, attachments – common block	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.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedBackgroundMaterial.Rema

			rks
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	For chemicals: 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). An empty template of the Excel file Residues trial table (primary and rotational crops) is available on the 'knowledge junction' (Template 6.3 (excel) DOI to be created on Zenodo) The uploaded file should not contain confidential material. For micro-organisms: Please include any information which may be available	Attachments list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	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	The assessment and conclusion of the applicant should be reported here. 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	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion.ExecutiveSummary

	htm or html document. 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 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] 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. 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). 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. 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. 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 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.]		

6.2.1-6.2.2 Non-viable or viable residues (magnitude in processed commodities)

Non-viable or viable residues (magnitude in processed commodities) - Endpoint summary

Purpose

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).

ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.AdministrativeDataSummary
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.AdministrativeDataSummary.DataProtection
Description of key information	Enter a short description of the most relevant endpoint data. The short description could include for example: - Information on ringlabels.	Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation
	Please make a statement whether: 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 specify the metabolites covered by this conclusion. 2) the magnitude of residues in processed commodities was sufficiently investigated in the context of the present dossier (according to current data requirements and to OECD Guideline No 508) and highlight data gap(s) and the non-standard uncertainty(ies), if any. 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. Key results used for the risk assessment	Rich text area	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.KeyInformation

	should be reported in the detailed tables below.		
Nature of residues in processed commodities	Summarise the results from standard hydrolysis studies. 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.NatureMagnitudeResidues ProcessedCommodities.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.NatureMagnitudeResidues ProcessedCommodities.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.NatureMagnitudeResidues ProcessedCommodities.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 specify the eventual data gaps).	Closed list with remarks (2000)	ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.Stable
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	Repeat this block to create one box per combination raw agricultural commodity (RAC)/processed commodity (PC) for which processing factors could be derived. This section can also be used to capture the distribution of residues in peel/pulp by derivation of process factor pulp/RAC.		ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.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.NatureMagnitudeResidues ProcessedCommodities.KeyInformation.ProcessingFactors.RelevantStudies
Raw agricultural	Raw agriculture commodity (RAC) means the product in or nearly in its natural state	Open list with remarks	ENDPOINT_SUMMARY.NatureMagnitudeResidues

commodity (RAC)	intended for sale or consumption without further processing. The term RAC means the same as "primary food commodity" or "primary feed commodity". Indicate the raw agricultural commodity (RAC) for which the processing factor is derived (e.g. apple). If not available, select 'other:' and specify.	(2000)	ProcessedCommodities.KeyInformation.ProcessingFactors.RawCommodity
Processed commodity (PC)	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. Indicate the processed commodity (PC) for which the processing factor is derived (e.g. apple juice). If not available, select 'other:' and specify.	Open list with remarks (2000)	ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.KeyInformation.ProcessingFactors.ProcessedCommodity
Number of trials	Indicate here the number of independent tests used to derive processing factors.	Integer	ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.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 the residue definition for enforcement (RD MO) and the residue level identified in the raw agricultural commodity according to enforcement residue definition (RD MO): PF MO = [residue concentration in Processed Com] RD MO/ [residue concentration in RAC] RD MO This factor is valid for the combination `procedure/commodity`, which was investigated in the processing study. Insert here the mean (of two studies) or	Decimal	ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.KeyInformation.ProcessingFactors.ProcessingFactorMo

	median (of more than 2 studies) value of all available processing factors for a given combination raw agricultural commodity (RAC)/processed commodity (PC). 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 processing factors shall reflect the enforcement residue definition in processed commodity.		
Median processing factor: RD RA	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: PF RA = [residue concentration in Processed Com] RD RA/ [residue concentration in RAC] RD MO. 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.	Decimal	ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.KeyInformation.ProcessingFactors.ProcessingFactorRa
Remarks	Please enter any additional remark for the processing factor, for example if the processing factor is tentative.	Multi-line text	ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.KeyInformation.ProcessingFactors.Remarks
Processing factors			
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.Discussion
	This section can be used to add any additional useful text.	Rich text area	ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.D

	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. If there is no additional information to be reported this field may be left empty.		iscussion.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 respective endpoint summaries of the detailed sections.		ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.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.NatureMagnitudeResidues ProcessedCommodities.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.NatureMagnitudeResidues ProcessedCommodities.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.NatureMagnitudeResidues ProcessedCommodities.Discussion.AttachedSanitisedDocsForPublication

Non-viable or viable residues (magnitude in processed commodities) - Endpoint study record

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

ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist: magnitude of residues in processed commodities	Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.Endpoint
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.DataSource
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 resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.ProductType
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.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	Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.StudyDesign.BulkRawAgriculturalCommodity

	(RAC). If not available, 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.MagnitudeResidInProcessedComm.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.MagnitudeResidInProcessedComm.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.MagnitudeResidInProcessedComm.MaterialsAndMethods.StudyDesign.FurtherDetailsOnStudyDesign
Sampling and analytical methodology		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.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.MagnitudeResidInProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleCollection
Details on sample handling and preparation	Include details on the sample handling and preparation. Use existing template and 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.	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndPreparation
Details on analytical methodology	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	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology

	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, you have 2 options on how to report the data: Option 1: please use the existing templates to report the following details on analytical method: 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 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. 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`		
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.MagnitudeResidInProcessedComm.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

	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). For chemicals: Please use the recommended formats as available in (DOI link to RESIDUE Template 6.1. (Tables in section 6.5.c/d)).	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)	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 'Details on sampling and analytical methodology').	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.StorageStabilityOfResiduesSampleIntegrity
Residues in RAC prior to processing		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing
Bulk RAC sub-sample sample no.	For chemicals: 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. Option 2: report directly the detailed information on the results in		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo

	RAC in the Excel file Processing trials table (DOI link to Template RESIDUE 6.5.) to be attached in the field below "Attached background material" For micro-organisms: 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		
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.MagnitudeResidInP

			rocessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_REC

			ORD.MagnitudeResidInProcessedComm.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)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ResidueLevelCalculated
Residue level (calculated and corrected)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.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	For chemicals: 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 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 (DOI link to RESIDUE Template 6.5.) for residues in processed commodities to be attached in the field below "Attached background material" For micro-organisms: 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.		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction
Processed fraction (PF sample)		Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAn

			dAspiratedGrainFractionsAGF.ProcessedFraction.ProcessedFractionPFSample
PF sample no.		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.PFSampleNo
Date of processing		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.DateOfProcessing
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalysisSampleID
Analysis sample description		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalysisSampleDescription
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsA

			ndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFraction

			sAGF.ProcessedFraction.AnalyteMeasured.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.CorrectionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ReferencePortion
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResiduLevelMeasured

Residue level (calculated)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResiduelevelCalculated
Residue level (calculated and corrected)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResiduelevelCalculatedAndCorrected
Analyte measured			
Processed fraction			
Aspirated grain fractions (AGF sample)	For chemicals: 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. Option 2: report directly the detailed information on the results for each AGF sample in the Excel file Processing trials table (DOI link to RESIDUE Template 6.5.) for residues in processed commodities to be attached in the field below "Attached background material". For micro-organisms: not relevant		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.MagnitudeResidInP

			rocessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.DateOfAGFSample
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalysisSampleID
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsA

			ndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesIn

			ProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.CorrectionByRecovery
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelMeasured
Residue level (calculated)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelCalculated
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.MagnitudeResidInProcessedComm.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks

Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication	For chemicals: 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' (DOI link to RESIDUE Template 6.5). The uploaded file should not contain confidential material. For micro-organisms: please upload sanitised documents for publication if required	Attachments list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached. Example: [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	Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ApplicantSummaryAndConclusion.ExecutiveSummary

	[simulated commercial practices]. 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 by studies showing that residues of [active ingredient] are stable in [crops/processed commodities] for up to [xx] days under frozen conditions. 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]. A comparison of the residues in the raw agricultural commodity (RAC) with those in each processed fraction resulted in processing factors of [processing factors] for [processed fractions], respectively. These processing factors [conform/did not conform] with the theoretical concentration factors.		

6.3 Summary and evaluation of residue behaviour resulting from data submitted under points 6.1 and 6.2

Purpose
Provide an overall conclusion on the residues (viable/non viable) 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 for specific purposes of application, such as "include an active substance in Annex IV".

ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs

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	Please provide an overall summary of the residues that are to be expected on edible commodities under GAP directed use(s) and provide evaluation of the anticipated exposure of consumers via dietary intake to toxicological relevant and significant residues. 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. For MRL applications, this rich text field should be used by the applicant to report, in accordance 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. 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	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.KeyInformation

	derive and propose a MRL shall be reported in Section 6.3.		
		Rich text area	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.KeyInformation.KeyInformation
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion
		Rich text area	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion.Discussion
Attached background material			ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.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.ResiduesInFoodAndFeedingstuffs.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	For chemicals: 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 not here. For micro-organisms: This field can be used to attach any useful supporting document. The MRL OECD calculator.xls, if available for the micro-organism viable and/or non-viable residues, shall be reported in section 6.2. as supporting information		
Attached (sanitised) documents for publication	Same as above with sanitized version for the document(s).	Attachments list	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion.AttachedSanitisedDocsForPublication

7 Fate and behaviour in the environment

The following documents are located under section 7 "Fate and behaviour in the environment:

7. Environmental fate and pathways – Endpoint summary

7.1 Persistence and multiplication: Additional information on environmental fate and behaviour Endpoint summary / Endpoint study record

7.1.1 Soil: Biodegradation in soil Endpoint summary / Endpoint study record

7.1.2 Water: Biodegradation in water and sediment: simulation tests Endpoint summary / Endpoint study record

7.1.3 Air: Phototransformation in air Endpoint summary / Endpoint study record

7.2 Mobility: Other distribution data Endpoint summary / Endpoint study record

Environmental fate and pathways - 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

ENDPOINT_SUMMARY.EnvironmentalFateAndPathways			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data summary – common block 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 orginal file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.Discussion

7.1 Persistence and multiplication

Persistence and multiplication - 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 persistence and multiplication (competitiveness) in soil, water and air.

ENDPOINT_SUMMARY.AdditionalInformationOnEnvironmentalFateAndBehaviour			
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

Persistence and multiplication - Endpoint study record

Purpose
Where relevant, appropriate information on the persistence and multiplication of the micro-organism, in all environmental compartments has to be given, unless it can be justified that exposure of the particular environmental compartment to the micro-organism is unlikely to occur. Special attention shall be given to

- competitiveness under the environmental conditions prevailing at and after the intended use, and
- population dynamics in seasonally or regionally extreme climates (particularly hot summer, cold winter and rainfall) and to agricultural practices applied after intended use.

Estimated levels of the specified micro-organism in a time course after use of the product under the proposed conditions of use shall be given.

This document can be used in cases where the soil, water and air documents are not suitable

ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour			
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.AdditionalInformationOnEnvironmentalFateAndBehaviour.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFate

			AndBehaviour.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour.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.AdditionalInformationOnEnvironmentalFateAndBehaviour.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInformationOnEnvironmentalFateAndBehaviour.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
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

7.1.1 Soil

Soil - 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 viability/population dynamics in soil and persistence in the terrestrial environment.

ENDPOINT_SUMMARY.BiodegradationInSoil			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the orginal file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil.Discussion

Soil - 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 pH (preferably measured in CaCl2) values, and where on the basis of other information, degradation or mobility are expected to be pH dependent, for example solubility and hydrolysis rate (see points 2.7 and 2.8), 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			
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
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'.	Closed 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	Integer	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAnd

	in field 'Report date'.		Methods.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.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.SoilNo
Soil type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.SoilType
% 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.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.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.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.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 (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Sand
% 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 (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.OrgC
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.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.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	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.CEC

		mal)	
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.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.BulkDensityGCm
% 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 is '<' or '<=='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.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.	Closed 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 substanc	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		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAnd

e concentration	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).		Methods.StudyDesign.InitialTestSubstanceConcentration
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.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	For each soil type, indicate the environmental conditions during the test if available or assumed in the model, if		ENDPOINT_STUDY_RECORD.Biodegradatio

conditions	estimated.		nInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.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		Header 1	ENDPOINT_STUDY_RECORD.Biodegradatio

discussion			nInSoil.ResultsAndDiscussion
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.	Closed 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.Biodegradatio

			nInSoil.ResultsAndDiscussion.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.ResultsAndDiscussion.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.ResultsAndDiscussion.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	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.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.BiodegradationInSoil.ResultsAndDiscussion.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.ResultsAndDiscussion.Degradation.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SoilNo
Sampling date	Enter date when the sample was taken	Date	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SamplingDate
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second	Range (Deci	ENDPOINT_STUDY_RECORD.Biodegradatio

	numeric field if the qualifier is '<' or '<=='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	mal)	nInSoil.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.HalfLifeOfParentCompound.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfPar

			entCompound.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 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'. Not relevant for microorganisms	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.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		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation

	provided in field 'Any other information on materials and methods incl. tables'.		
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.BiodegradationInSoil.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.BiodegradationInSoil.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.BiodegradationInSoil.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.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.EvaporationOfParentCompound
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.BiodegradationInSoil.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.BiodegradationInSoil.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 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)	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.DetailsOnResults

	with the full degradation or elimination curves. 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. STERILE TREATMENTS: If used, report the transformation of the 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.BiodegradationInSoil.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 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.BiodegradationInSoil.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the orginal 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.	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

7.1.2 Water

Water - 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 related to the
Chemicals: persistence in water systems (bottom sediment and water, including suspended particles);
Microorganisms: viability/population dynamics in natural sediment/water systems

ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block DT90 values should also be reported	Header 1	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.AdministrativeDataSummary
Key value for chemical safety assessment	Only to be completed if such data exists Report DT50 values for the different compartments and the temperature in °C	Header 1	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment
Half-life in freshwater		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.HalflifeInFreshwater
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.AtTheTemperatureOfFreshwater
Half-life in marine water	Not relevant for EU_PPP	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.HalflifeInMarineWater
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.AtThe

			TemperatureOfMarineWater
Half-life in freshwater sediment		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.HalflifeInFreshwaterSediment
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.AtTheTemperatureOfFreshwaterSediment
Half-life in marine water sediment		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.HalflifeInMarineWaterSediment
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.AtTheTemperatureOfMarineWaterSediment
Whole System		Header 2	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.WholeSystem
			ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.WholeSystem.HalfLifeInWholeSystem
Half-life in whole system		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.WholeSystem.HalfLifeInWhol

			eSystem.HalfLifeInWholeSystem
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.WholeSystem.HalfLifeInWholeSystem.AtTheTemperatureOfWholeSystem
Type of system		Open list	ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests.KeyValueForChemicalSafetyAssessment.WholeSystem.HalfLifeInWholeSystem.TypeOfSystem
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.BiodegradationInWaterAndSedimentSimulationTests.Discussion

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			
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 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	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods
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 O2 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 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.	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 elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.DetailsOnSourceAndPropertiesOfSurfaceWater
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 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
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 relevant details on radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.ParameterFollowedForBiodegradationEstimation
Details on analytical	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	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTes

methods	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.		ts.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
Reference substance	Indicate identity of reference substance(s) used and give details in the supplementary remarks field as appropriate. Repeat field for each substance.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.MaterialsAndMethods.StudyDesign.ReferenceSubstance.ReferenceSubstance
Reference 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.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,		ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTes

	also specify 'Total recovery in abiotic control measured at end of test' and 'Total recovery in biologically active treatment at end of test'.		ts.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 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.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.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.M

			eanTotalRecovery.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 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'.		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 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 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.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 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.HalfLifeOfParentCompound5

			0DisappearanceTimeDT50.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.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 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.BiodegradationInWaterAndSedimentSimulationTests.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 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.BiodegradationInWaterAndSedimentSimulationTests.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.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.IdentityTransformation.Refer

			enceSubstance
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.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.EvaporationOfParentCompound
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 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.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.ResultsAndDiscussion.DetailsOnResults

	(use predefined table if any) or other appropriate table. STERILE TREATMENTS: If used, report the transformation of the 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 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.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the orginal file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInWaterAndSedimentSimulationTests.OverallRemarksAttachments
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.O

			bservedValue

7.1.3 Air

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			
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 microoganisms indicate if concentration in air are observed	Header 1	ENDPOINT_SUMMARY.PhototransformationInAir.AdministrativeDataSummary
Key value for chemical safety assessment	Only to be completed if such data exists	Header 1	ENDPOINT_SUMMARY.PhototransformationInAir.KeyValueForChemicalSafetyAssessment
Half-life in air		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.PhototransformationInAir.KeyValueForChemicalSafetyAssessment.HalflifeInAir
Degradation rate constant with OH radicals		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.PhototransformationInAir.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 orginal file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_SUMMARY.PhototransformationInAir.Discussion

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

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			
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.MaterialsAndMethods.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 the photodegradation was estimated, e.g. the photochemical reaction with OH radicals, include details	Text templ	ENDPOINT_STUDY_RECORD.Phototransforma

(if used)	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/cm³' - Degradation rate constant: e.g. '18.3 x 10E-12 cm³/(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'	ate	tionInAir.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
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	ENDPOINT_STUDY_RE

		measure with Closed List (Decimal)	CORD.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			
Reference substance	Indicate whether the results with the reference substance(s) are valid.	Closed 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	Multi-line	ENDPOINT_STUDY_RECORD.Phototransforma

	container).	text	tionInAir.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 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.PhototransformationInAir.ResultsAndDiscussion.SpectrumOfSubstance.Parameter
Value	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.SpectrumOfSubstance.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	Open list with remar	ENDPOINT_STUDY_RECORD.PhototransformationInAir.ResultsAndDiscussion.SpectrumOfSub

	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:'	ks (2000)	stance.RemarksOnResults
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.PhototransformationInAir.ResultsAndDiscussion.Degradation
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.PhototransformationInAir.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.PhototransformationInAir.ResultsAndDiscussion.Degradation.Degr
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 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.	Check box	ENDPOINT_STUDY_RECORD.PhototransformationInAir.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.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.ResultsAndDis

			cussion.DegradationRateConstant
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.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
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	Closed list	ENDPOINT_STUDY_RECORD.Phototransforma

	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.		tionInAir.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.IdentityTransformation.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

7.2 Mobility

Mobility - 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			
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
Additional information	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 If there is no additional information to be reported this field may be left empty.	Header 1	ENDPOINT_SUMMARY.OtherDistributionData.Discussion

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)

Mobility - 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			
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	Material and methods – common block	Header 1	ENDPOINT_STUDY_REC

methods	Applicable test guideline: OECD Test Guideline 312: Leaching in Soil Columns.		ORD.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.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

8 Effects on non-target organisms

The following documents are located under section 8 "Effects on non-target organisms:

Effects on non-target organisms – Flexible summary

8.1 Effects on birds: Toxicity to birds EU_PPP Endpoint summary / Toxicity to birds Endpoint study record

8.2 Effects on aquatic organisms – Endpoint summary

8.2.1 Effects on fish

8.2.1.1 Short-term toxicity testing on fish: Short-term toxicity to fish EU_PPP Endpoint summary / Short-term toxicity to fish Endpoint study record

8.2.1.2 Long-term toxicity testing on fish: Long-term toxicity to fish EU_PPP Endpoint summary / Long-term toxicity to fish Endpoint study record

8.2.2 Effects on fresh water invertebrates

8.2.2.1 Short-term toxicity testing on aquatic invertebrates: Short-term toxicity to aquatic invertebrates EU_PPP Endpoint summary / Short-term toxicity to aquatic invertebrates Endpoint study record

8.2.2.2 Long-term toxicity testing on aquatic invertebrates: Long-term toxicity to aquatic invertebrates EU_PPP Endpoint summary / Long-term toxicity to aquatic invertebrates Endpoint study record

8.2.3 Effects on algae growth: Toxicity to aquatic algae and cyanobacteria EU_PPP Endpoint summary / Toxicity to aquatic algae and cyanobacteria Endpoint study record

8.2.4 Effects on plants other than algae: Toxicity to plants EU_PPP Endpoint summary / Toxicity to plants Endpoint study record

8.2.5 Inhibition of microbial activity: Toxicity to microorganisms Endpoint summary / Toxicity to microorganisms Endpoint study record

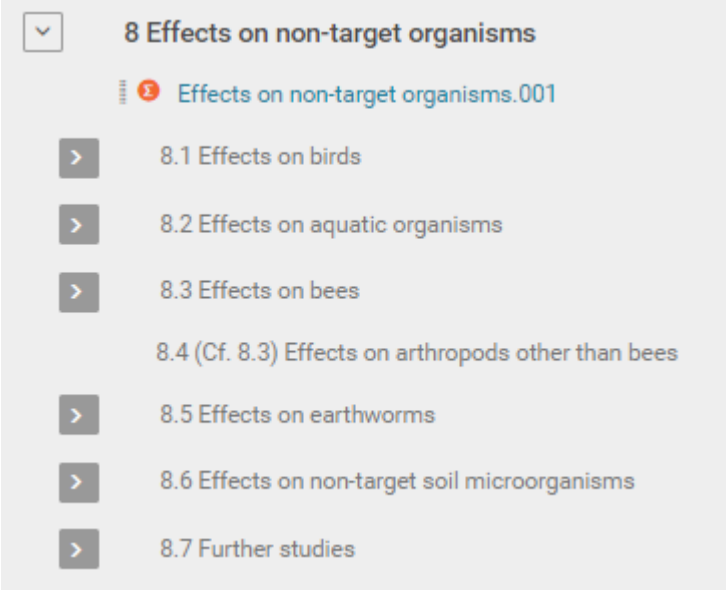
8.3 Effects on bees: Toxicity to terrestrial arthropods EU_PPP Endpoint summary / Toxicity to terrestrial arthropods Endpoint study record

8.5 Effects on earthworms: Toxicity to soil macroorganisms except arthropods EU_PPP Endpoint summary / Toxicity to soil macroorganisms except arthropods Endpoint study record

8.6 Effects on non-target soil microorganisms: Toxicity to soil microorganisms (EU PPP) Endpoint summary / Toxicity to soil microorganisms Endpoint study record

8.7 Further studies: Additional ecotoxicological information Endpoint summary / Endpoint study record

8.7.1 Terrestrial plants: Toxicity to terrestrial plants EU_PPP Endpoint summary / Endpoint study record



Effects on non-target organisms - Flexible record

Purpose
The information provided for the micro-organism, together with other relevant information, and that provided for one or more preparations containing it, shall be sufficient to:
- decide whether, or not, the micro-organism can be approved,
- specify appropriate conditions or restrictions to be associated with any approval,
- permit an evaluation of short- and long-term risks for non-target species — populations, communities, and processes — as appropriate,
- classify the micro-organism as to biological hazard,
- specify the precautions necessary for the protection of non-target species, and
- specify the pictograms (once introduced), signal words, and relevant hazard and precautionary statements for the protection of the environment, to be mentioned on packaging (containers).

FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides			
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 in the format for section Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1) of the List of Endpoints can be included in this section	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. Table in the format for section Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1) of the List of Endpoints	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentWildMammals.field8618

	can be included in this section		
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 in the format for section Toxicity**/**exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2) of the List of Endpoints can be included in this section	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. Report Trigger values (HQ and ETR)	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. Report Trigger values (HQ and ETR)	Rich text area	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides.EcotoxRiskAssessmentPesticides.RiskAssessmentNonBees.field5875
Risk assessment		Header 2	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticid

to non-target soil meso- and macrofauna			es.EcotoxRiskAssessmentPesticides.RiskAssessmentSoilMesoMacrofauna
	Provide a summary of the risk assessment to soil meso- and macroorganisms living in the soil. A table of Toxicity/exposure rations for soil organisms in the format of the List of Endpoints can be included in this section	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 risk assessment to non-target terrestrial plants. A table in the format for section Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6) of the list of endpoints can be included in this section.	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 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 Effects on birds

Effects on birds - 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, including:
- 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			
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 assessm		Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa

ent			
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 (species)	Select the organism(s) for which the endpoint was derived.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.ShortTermToxicity.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.ShortTermToxicity.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.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_PPP.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_PPP.KeyValueForCsa.ShortTermToxicity.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) also must be reported.	Range with closed list (Decimal)	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.ShortTermToxicity.EffectConcentration
Short-term toxicity to birds			
Long-			ENDPOINT_SUMMAR

term toxicity to birds			Y.ToxicityBirds_EU_PPP.KeyValueForCsa.LongTermToxicity
Study name / type	Select the study for which the endpoint was derived.	Endpoint reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.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_PPP.KeyValueForCsa.LongTermToxicity.TestOrganismsSpecies
Parent / metabolite	Indicate whether the endpoint is for the active substance or a metabolite.	Closed list	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.KeyValueForCsa.LongTermToxicity.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.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_PPP.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_PPP.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_PPP.KeyValueForCsa.LongTermToxicity.EffectConcentration
Long-term toxicity to birds			
Higher tier	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_P

testing for safety assessment			PP.HigherTierTesting
		Rich text area	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.HigherTierTesting.field1350
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP.Discussion

Effects on birds - 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 (LD_{50}) of the active substance. The study shall provide, where possible, LD_{50} values. The lethal threshold dose, time courses of response and recovery, the LD_{10} and LD_{20} shall be reported together with the no observed effect level (NOEL) and gross pathological findings. Where LD_{10} and LD_{20} cannot be estimated, an explanation shall be provided. Study design shall be optimised for the achievement of an accurate LD_{50}.

A study shall be provided establishing the short-term dietary toxicity. LC_{50} 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. LC_{50} and NOEC values shall be converted to daily dietary dose (LD_{50}) 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 EC_{10} and EC_{20} 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			
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	Material and methods – common block	Header 1	ENDPOINT_STUDY_REC

methods	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		ORD.ToxicityToBirds.MaterialsAndMethods
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 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	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.TestMaterials.DetailsOnPreparationAndAnalysisOfDiet

	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.		
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
No. of animals	Indicate the post-observation period	Multi-line text	ENDPOINT_STUDY_REC

per sex per dose and/or stage	(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.		ORD.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
Nominal and measured doses / concentrations	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. For micro-organisms, average achieved dose in colony forming units (cfu) also must be reported.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.StudyDesign.NominalAndMeasuredDosesConcentrations
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.ToxicityToBirds.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions
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 the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.MaterialsAndMethods.Examinations.DetailsOnReproductiveParameters
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 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	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.EffectLevel

	appropriate qualifier(s) if applicable.		
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 include further details in the supplementary remarks field, e.g. 'related to number of eggs or young surviving'.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectLevels.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 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 an excerpt	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.MortalityAndSubLethalEffects

	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.		
Effects on reproduction	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.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToBirds.ResultsAndDiscussion.EffectsOnReproduction
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.AnyOtherInformationOnResult

			sInclTables
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
EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438. https://www.efsa.europa.eu/en/efsajournal/pub/1438 10.2903/j.efsa.2009.1438

8.2 Effects on aquatic organisms

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:

Toxicity endpoints (such as LC50, EC10, EC20, EC50 and NOEC) shall be calculated on the basis of nominal or mean/initial measured concentrations.

Information on toxicity, infectiveness and pathogenicity to aquatic organisms must be reported

ENDPOINT_SUMMARY.AquaticToxicity			
Name	**Instructions**	**Data Type**	**Field path**
Administrative data	Administrative data summary – common block Conclude on the effects on aquatic organisms	Header 1	ENDPOINT_SUMMARY.AquaticToxicity.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AquaticToxicity.Discussion

Links to support materials
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, noted 15 January 2015) https://www.efsa.europa.eu/en/efsajournal/pub/3290 10.2903/j.efsa.2013.3290

OECD (2018). Guidance document on aqueous-phase aquatic toxicity testing of difficult test chemicals. OECD Series on Testing and Assessment No. 23 (Second edition) http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2000)6/REV1&docLanguage=En

8.2.1 Effects on fish

8.2.1.1 Short-term toxicity testing on fish

Short-term toxicity testing on 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			
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.ShortTermToxicityFreshwaterFish.ParentMetabolite
Substance	Select the substance for which the endpoint was derived.	Entity reference field	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwa

			terFish.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 assessed (EC50, LC50 or NOEC).	Closed list	ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP.KeyValueForCsa.ShortTermToxicityFreshwaterFish.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.ShortTermToxicityFreshwaterFish.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.ShortTermToxicityFreshwaterFish.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/oecd/oecd-gd126.pdf

Short-term toxicity testing on fish - Endpoint study record

Purpose
A study shall be provided on the acute toxicity to fish (LC_{50}) and details of observed effects. Information on toxicity, infectiveness and pathogenicity to fish must be reported

ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish			
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
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.MaterialsAndMet

			hods.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.	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 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 tail-bud 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_RECORD.ShortTermToxicityToFish.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.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	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide	Text templ	ENDPOINT_STUDY_RECORD.ShortTermToxicity

reference substance (positive control)	relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.	ate	ToFish.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		Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Sublethal observations / clinical signs	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. Optionally include clinical signs, using predefined (or other) table as proposed in TG 203, Annex 4. Percentages of test animals that showed symptomology. 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.	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

8.2.1.2 Long-term toxicity testing on fish

Long-term toxicity testing on 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.LongTermToxicityToFish_EU_PPP			
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	Select the basis for effect from which the endpoint	Multi	ENDPOINT_SUMMARY.LongT

for effect	was derived. If not available, select 'other:' and enter name of the basis for effect.	select open list with remarks	ermToxicityToFish_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			
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	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP.Di

informa tion			scussion

Long-term toxicity testing on 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			
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 OCSPP 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.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.) 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_RECORD.LongTermToxToFish.ResultsAndDiscussion
Any other information on results incl.	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.LongTermToxToFish.ResultsAndDiscussion.

tables			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

8.2.2 Effects on fresh water invertebrates

8.2.2.1 Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on 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			
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
Test organisms	Select species from picklist. If not available, select 'other:' and enter name of organism (species).	Multi select open	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.KeyValueCsa.Sh

(species)		list with remarks	ortTermToxAquaInvertebrates.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 invertebrates			
Higher tier testing for safety	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP.HigherTierTesting

assessment			
		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

Short-term toxicity testing on 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 (EC_{50}) 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			
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.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.DataSource.Reference
Materials and	Material and methods – common block Applicable test guidelines:	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.DataSource.Reference

methods	OECD Test Guideline 202: *Daphnia sp.* Acute Immobilisation Test US EPA OCSPP 850.1035 Mysid Acute Toxicity Test OECD Test Guideline 235: *Chironomus sp.*, Acute Immobilisation Test OPPTS 885.4240 Freshwater Aquatic Invertebrate Testing, Tier I		icityToAquaInv.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.TestMaterials.TestMaterialInformation
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.TestConditions
Any other information 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.	Header 2	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
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.Result

			sAndDiscussion.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.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
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	Open list with	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.Result

	supplementary remarks field.	remarks	sAndDiscussion.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.ShortTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	For micro-organisms, information on toxicity, infectiveness and pathogenicity to freshwater invertebrates 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 field 'Attached background material'. Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.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.ShortTermToxicityToAquaInv.ResultsAndDiscussion.ResultsRefSubstance
Reported	Indicate the parameters analysed, the statistical method	Multi-	ENDPOINT_STUDY_R

statistics and error estimates	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.	line text	ECORD.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.OveralIRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv.ApplicantSummaryAndConclusion

8.2.2.2 Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on 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.LongTermToxicityToAquaticInvertebrates_EU_PPP [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_PP

			P.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
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	Half-bounded with	ENDPOINT_SUMMARY.L

	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	closed list (Decimal)	ongTermToxicityToAquaticInvertebrates_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 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

Long-term toxicity testing on 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.

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: *Daphnia magna* 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.Materi

			alsAndMethods.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
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.AnyOtherInformationOnMaterialsAndMethodsInclTables
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

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; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering	Open list with remarks	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ResultsAndDiscussion.EffectConcentrations.Remark

	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'.	(2000)	sOnResults
Effect concentrations			
Details on results	For microorganisms:Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported. 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. 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.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
Attached background material			
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv.ApplicantSummaryAndConclusion

8.2.3 Effects on algae growth

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			
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 /	Select the study from which the endpoint was derived.	Endpoint	ENDPOINT_SUMMARY.ToxicityToAquaticAl

type		reference field	gae_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 = 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

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			
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
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
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.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectConcentrations.KeyResu

			lt
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 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	Open list with remar	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.EffectCo

	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'.	ks (2000)	ncentrations.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 field 'Attached background material'. Note: Specific tables may be required.	Text templ ate	ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae.ResultsAndDiscussion.ResultsDetails
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 templ ate	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	Any other information on results incl. tables Block	Heade	ENDPOINT_STUDY_R

information on results incl. tables		r 2	ECORD.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

8.2.4 Effects on plants other than algae

Effects on plants other than algae - 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			
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
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_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

Effects on plants other than algae - 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			
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.DataSource

Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.DataSource.Reference
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 221: *Lemna sp.* Growth Inhibition Test ASTM E1913-04: Standard Guide for Conducting Static, Axenic, 14-Day Phytotoxicity Tests in Test Tubes with the Submersed Aquatic Macrophyte, *Myriophyllum sibiricum Komarov* OECD Test Guideline 238: Sediment-Free *Myriophyllum Spicatum* Toxicity Test OECD Test Guideline 239: Water-Sediment *Myriophyllum Spicatum* 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.MaterialsAndMethods.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.	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.MaterialsAndMethods.Any

tables			OtherInformationOnMaterialsAndMethodsInclTables
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
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	Open	ENDPOINT_STUDY

	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.	list with remarks	_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 with remarks	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.BasisForEffectMulti
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.ToxicityToAquaticPlant.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	Any abnormal adverse or beneficial effects in treatment and/or control groups, including dates and times the effects were observed, 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 or other appropriate table(s) if available,	Text template	ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant.ResultsAndDiscussion.ResultsDetails

	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

8.2.5 Inhibition of microbial activity

Inhibition of microbial activity - Endpoint summary

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:** additional studies might include further acute studies on additional species or processes (such as sewage systems) or higher tier studies such as chronic, sub-lethal or reproductive studies on selected non-target organisms.

ENDPOINT_SUMMARY.ToxicityMicroorganisms v.5.0			
Name	**Instructions**	**Data type**	**Field path**
Administrativ	Administrative data summary –	Header 1	ENDPOINT_SUMMARY.ToxicityMi

e data	common block Conclude on the effect on biological methods for sewage treatment (activated sludge and *Pseudmonas sp*)		croorganisms.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityMicroorganisms.KeyValueForChemicalSafetyAssessment
EC50 for microorganisms	Enter EC50 value (if available)	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.ToxicityMicroorganisms.KeyValueForChemicalSafetyAssessment.KeyValue1
EC10 or NOEC for microorganisms	Enter EC10 or NOEC value (if available)	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.ToxicityMicroorganisms.KeyValueForChemicalSafetyAssessment.KeyValue2
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicityMicroorganisms.Discussion

Inhibition of microbial activity - 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

ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms			
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 is relevant for this endpoint	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
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

8.3 Effects on bees

Effects on bees - 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 species;
- Route/time-scale
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects);
- Test type (laboratory/others);
- Dose (kg /ha).

This summary can be used to conclude on the effects on bees and other arthropods. Separate summary documents can be created for each endpoint

ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP			
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
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	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP.KeyValueF

	name of the basis for effect.		orCsa.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
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.LongTermToxTerr

			estrialArthropods.Parent Metabolite
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 µg/bee/day, µg/larva/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 or field studies for the different taxa). Is there potential for accumulative toxicity	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
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-

Effects on 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 LD_{50} 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 LD_{50} 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 EC_{10}, EC_{20}, EC_{50} together with the NOEC. Where the chronic oral EC_{10}, EC_{20}, EC_{50} 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 EC_{10}, EC_{20} and EC_{50} for adult bees, where possible, and larvae together with the NOEC. Where EC_{10}, EC_{20}, EC_{50} 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 2020]			
Name	**Instructions**	**Data type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.AdministrativeData
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.DataSourc

			e.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 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	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.MaterialsAndMethods
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. 'Hymenoptera (honeybees)' for honeybees or 'Collembola (soil-dwelling springtail)' for a test with Folsomia candida. Helpful for searching purposes.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.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	Results and discussion BLOCK (OHT:	Header 1	ENDPOINT_STUDY_REC

discussion	Aquatic / Terrestrial tox.)		ORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion
Toxic reference	Specify the toxic reference considered in the study.	Text area	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.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 weighted average = TWA), measured (not specified), acid equivalent or estimated. Select 'not specified' if not known.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.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	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn

	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.		
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 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.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	For microorganisms indicate that information on toxicity, infectiveness and pathogenicity to bees and arthropods other than bees must be reported. The text from the US EPA guideline could also be included afterwards. The guideline should be cited (885.4340 - Nontarget Insect	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods.ResultsAndDiscussion.ResultsDetails

	Testing, Tier I (February 1996)). 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. 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 characterisation (to guarantee the proper exposure). 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). 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). 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'). Ability to record multiple endpoint values (we can have different species, populations, communities etc.)		

	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 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.		
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.ToxicityToTerrestrialArthropods.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.ToxicityToTerrestrialArthropods.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

8.5 Effects on earthworms

Effects on earthworms - 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 species;
- Route/time-scale
- Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects);
- Test type (laboratory/others);
- Dose (kg /ha).

Information on toxicity, infectiveness and pathogenicity to earthworms must be reported.

ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP			
Name	**Instructions**	**Data type**	**Field path**
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 *Eisenia fetida* (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	Select the species from the picklist. If not available,	Multi	ENDPOINT_SUMMARY.Tox

organisms (species)	select 'other:' and enter the species name of the test organism.	select open list with remarks	icitySoilMacroorganisms_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
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 macroorga			

nisms 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 field	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.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	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.BasisForEffect

		remarks	
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 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.	Half-bounded with open list (Decimal)	ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP.KeyValueForCsa.LongTermToxicitySoilOrganisms.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

Effects on earthworms - 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 EC_{10}, EC_{20} 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			
Name	**Instructions**	**Data type**	**Field path**
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 (*Eisenia fetida/Eisenia andrei*) 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
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	Results and discussion BLOCK (OHT: Aquatic /	Heade	ENDPOINT_STUDY_REC

and discussion	Terrestrial tox.)	r 1	ORD.ToxicityToSoilMacroorganismsExceptArthropods.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.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	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn

	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.		
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 substance (positive	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.ToxicityToSoilMacroorganismsExceptArthropods.ResultsAndDiscussion.ResultsRefSubstance

control)			
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

8.6 Effects on non-target soil microorganisms

Effects on non-target soil microorganisms - 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			
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		Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.KeyValueForChemicalSafetyAssessment

assessment			
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
Long-term toxicity to soil microorganisms			
Higher tier testing for	Provide information about higher tier testing (e.g. modelling or field studies for the different taxa).	Header 1	ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP.HigherTierTesting

safety assessment			
		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

Effects on non-target soil microorganisms - 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			
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.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.DataSource.Reference
Materials	Material and methods – common block	Heade	ENDPOINT_STUDY_R

and methods	Applicable test guideline: OECD Test Guideline 216: Soil Microorganisms: Nitrogen Transformation Test OPPTS 850.5100 Soil Microbial Community Toxicity Test	r 1	ECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.TestMaterials.TestMaterialInformation
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.TestOrganisms
Test organisms (inoculum)	Select 'soil' if soil samples were used as inoculum. Otherwise select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.TestOrganisms.TestOrganismsInoculum
Study design	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.StudyDesign
Test conditions	Study design BLOCK (OHT: Terrestrial tox.)	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.TestConditions
Any other information on materials and methods incl.	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

tables			
Results and discussion	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.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_RECORD.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.	Check box	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.KeyResult
Duration	Enter numeric value and unit .	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.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_RECORD.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_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.	Closed 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	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.ConcBasedOn

	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.		
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: - 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.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	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. 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	Text template	ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms.ResultsAndDiscussion.ResultsDetails

	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. 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

8.7 Further studies

Further studies - 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.

ENDPOINT_SUMMARY.AdditionalEcotoxicologicalInformation			
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

Further studies - 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			
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.Resul

			tsAndDiscussion
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

8.7.1 Terrestrial plants

Terrestrial 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.

ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP			
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 appropriate include further details in the supplementary remarks field.	Multi select open list with remarks	ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP.KeyValueCsa.ToxTerrestrialPlants.BasisForEffect
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-

Terrestrial plants - Endpoint study record

Purpose
A test shall provide the ER_{50} 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			
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 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 organism	Indicate the species and corresponding plant group. As appropriate you can prepare a study summary for each	Header 2	ENDPOINT_STUDY_RECORD.ToxicityToTer

s	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.		restrialPlants.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 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.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	Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)	Header 1	ENDPOINT_STUDY_RECORD.ToxicityToTer

discussion			restrialPlants.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.	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 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.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.ConcBas

	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.		edOn
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 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.ToxicityToTerrestrialPlants.ResultsAndDiscussion.EffectConcentrations.RemarksOnResults
Effect concentrations			
Details on results	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. 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 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').	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.ResultsAndDiscussion.ResultsDetails

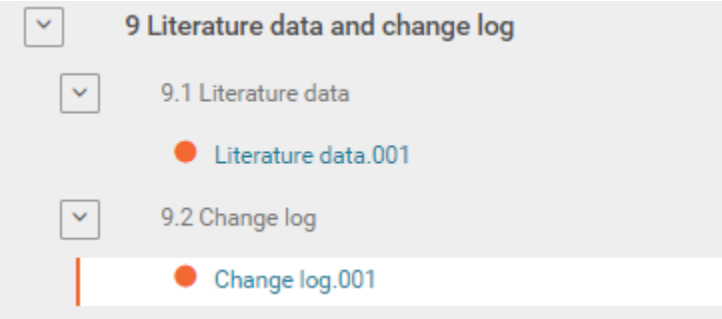
	As appropriate also attach a figure with growth curves in field 'Attached background material'.		
Results with reference substance (positive control)	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants.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.ToxicityToTerrestrialPlants.ResultsAndDiscussion.Statistics
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

9 Literature data and change log

The following documents are located under section 9 "Literature data and change log"

9.1 Literature data - Flexible record

9.2 Change log – Flexible record



9.1 Literature data

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

FLEXIBLE_RECORD.LiteratureSearch			
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	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. An appropriate Endpoint Study Record should be completed for each relevant study and the literature reference included in the data source section.	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 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	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.KeyInformationDesc

Overall summary of the literature search	Summary of the methodology used to retrieve relevant studies on side-effects on health, the environment and non-target species. Report the criteria used to classify the references as being clearly non-relevant (e.g. not related to pesticides). Report the criteria used to assess the reliability of the studies.	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 information on databases/sources Is provided in the supporting materials below	Open list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.SearchService
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	The search strings used to retrieve the records e.g. 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	Multi-line text	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Strings

	More examples are provided in the supporting materials below		
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
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.NoDetailAssessment
Reliable studies	Report the number of records retained after the reliability assessment	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationO

			fTheReview.ReliableStudies
Evaluated studies	Number of studies included in the dossier, reported in an endpoint study record and used as supporting information. These studies should be listed in the Literature reference(s) field and the number should be the same.	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.EvaluatedStudies
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 literature searches can be uploaded here in RIS format or as an Excel table containing bibliographic information.	Single file attachment	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial.Attachment

Remarks	Indicate the source of the contents of the file and the format type.	Text	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial.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

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			
Name	**Instructions**	**Data type**	**Field path**
General information	See administrative data	Header 1	FLEXIBLE_RECORD.ChangeLog.GeneralInformation
	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 authorisations. 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			

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.

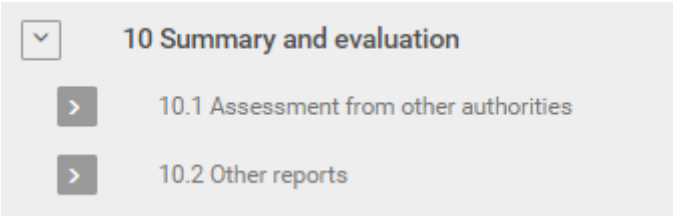
COMMISSION IMPLEMENTING REGULATION (EU) 2020/1740 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R1740.

10. Summary and evaluation

The following documents are located under section 10 "Summary and evaluation"

10.1 Assesment from other authorities – Flexible record

10.2 Other reports - Flexible record



10.1 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			
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
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)	Check the current existing RD in the EU MRL data base.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues

	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 If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.		.MonitoringPurposesPlant
Risk assessment (plant)	The field refers to the risk assessment residue definitions for plant commodity/ies for which the MRL application is submitted. If different risk assessment residue definitions are set in different plant commodities under consideration, this shall be indicated. If for processed commodities residue definitions differ from residue definitions in raw agricultural commodity (RAC), this shall be indicated. If for rotational crops the residue definition differs from the residue definition in primary crops, this shall be indicated. Available in EFSA ccl and Registration reports	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.RiskAssessmentPlant
Monitoring purposes (animal)	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 If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated. Please check the current existing RD in the EU MRL data base.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.MonitoringPurposesAnimal
Risk assessment (animal)	The field refers to the risk assessment residue definitions for animal commodity/ies for which the MRL application is submitted. If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated. Available in EFSA ccl and Registration reports	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.RiskAssessmentAnimal

Remarks	Any comment on the existing RD for risk assessment (e.g. provisional, clarify the source, data gaps, …)	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.Remarks
EFSA paramCode			FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.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		Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl
EU MRL	List the existing EU MRLs for this active substance		FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl
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
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

Risk assessment (plant)	The field refers to the risk assessment residue definition in in the exporting country in the plant commodity for which the MRL application is submitted. If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated. 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.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.RiskAssessmentPlant
Monitoring purposes (animal)	The field refers to the enforcement residue definition in the exporting country for the animal 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.MonitoringPurposesAnimal
Risk assessment (animal)	The field refers to the risk assessment residue definition in the exporting country for the animal commodity for which the MRL application is submitted. If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.RiskAssessmentAnimal
Remarks	Any comment on the existing RD for risk assessment (e.g. provisional, clarify the source, data gaps, …)	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
Country	Select the exporting country from the list	Multi select	FLEXIBLE_RECORD.AssessmentOtherAuthorities.Assessm

		open list	entsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Country
Commodity	The commodity plant parts which were analysed for and for which results should be reported in this table. 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..	Multi select open list with remarks	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Commodity
MRL value	If MRL setting processes are established in exporting countries. If MRL setting processes are not established in exporting countries, specify if Codex residue limit (CXL) is applicable. If there are no CXL and no MRL in the exporting country, report 'not relevant' and specify the reason in remark box.	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	Any additional remark on the MRL in the exporting country. If MRL setting processes are not established in exporting countries, specify if Codex residue limit (CXL) is applicable. If no CXL and no MRL in the exporting country, report 'not relevant' and specify the reason in remark box.	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
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

10.2 Other reports

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			
Name	**Instructions**	**Data type**	**Field path**
Administrative	See administrative data	Header 1	FLEXIBLE_SUMMARY.Su

data			mmaryEvaluation_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 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

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

Name	Instructions	Type	Field Path
	Set confidentiality and regulatory program flags.	Confidentiality	REFERENCE_SUBSTANCE.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_SUBSTANCE.ReferenceSubstanceName
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_SUBSTANCE.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_SUBSTANCE.Description
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
Remarks		Text	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Remarks
Synonyms			
Molecular and structural information		Header 1	REFERENCE_SUBSTANCE.MolecularStructuralInfo
		Confidentiality	REFERENCE_SUBSTANCE.MolecularStructuralInf

			o.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
InChl	The IUPAC international chemical identifier https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.InChl
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) For machine readable files the format should be .sk2 or .cdx or .mol For image files the format should be jpg or png		REFERENCE_SUBSTANCE.MolecularStructuralInfo.ChemicalStructureFiles
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

Links to support materials
CIPAC number: https://cipac.org/index.php/code-numbers/navigate-code-numbers
https://www.cas.org/support/documentation/chemical-substances
http://doi. paramCode - European Food Safety Authority. (2020). Harmonized terminology for scientific research [Data set]. Zenodo. org/10.5281/zenodo.3243215
https://iupac.org/who-we-are/divisions/division-details/inchi/
https://www.iso.org/committee/50160/x/catalogue/
http://www.alanwood.net/pesticides/index_cn_frame.html
https://cactus.nci.nih.gov/chemical/structure/
https://iuclid6.echa.europa.eu/inventories-iuclid

UUID: 4f1c5970-dede-40e3-a833-15800a404834

Reference substance name*
DIFLUBENZURON

Inventory

Inventory number
EC / 252-529-3 / N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide / 35367-38-5 / C14H9ClF2N2O2

No inventory information available

Justification
None

Reference substance information *None* *None*

IUPAC name
1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea

Description
1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea

Synonyms + New item

#...	Identifier	Identity	Remarks	Action
1	other: CIPAC number	339	*None*	
2	other: ISO common name	Diflubenzuron	E-ISO, (m) F-ISO, ANSI, ESA	

CAS information

CAS number
35367-38-5

CAS name
None

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
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	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. Click on New Item and set values. See Confidentiality Requests.	LEGAL_ENTITY.Identifiers
Contact information	An address can be defined for a contact person of the Legal entity and links can be made to one or more Contact entities	LEGAL_ENTITY.ContactInfo
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

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
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

Purpose
Storage of bibliographic metadata with attached documents including full study reports and published scientific papers
Linking studies to the Notification of Studies Database
Used as the data source in OECD harmonised templates and DOMAIN Endpoint Study Records
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).

Name	Instructions	Type	Field Path
General information		Header 1	LITERATURE.GeneralInfo
Reference Type	Select 'study report' for a full study report used as a data source for an endpoint study record. Select 'published' for relevant studies identified from a literature search to address data requirements The other reference types can also be used	Open list	LITERATURE.GeneralInfo.LiteratureType
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 be used for scientific assessment purposes only. The uploaded attachment will not be included in published dossier	Attachments list	LITERATURE.GeneralInfo.AttachedDocuments
Attached (sanitised) documents for publication	For study reports a sanitised version of the full study report must be uploaded in this field in PDF format. 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. The uploaded attachment will be included in the published dossier	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	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'. This section should be used to include justifications for study belayed notifications.	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

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

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 specification can be indicated for the active substance and impurities	Text template	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.ConfidentialDetailsOnTestMaterial

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

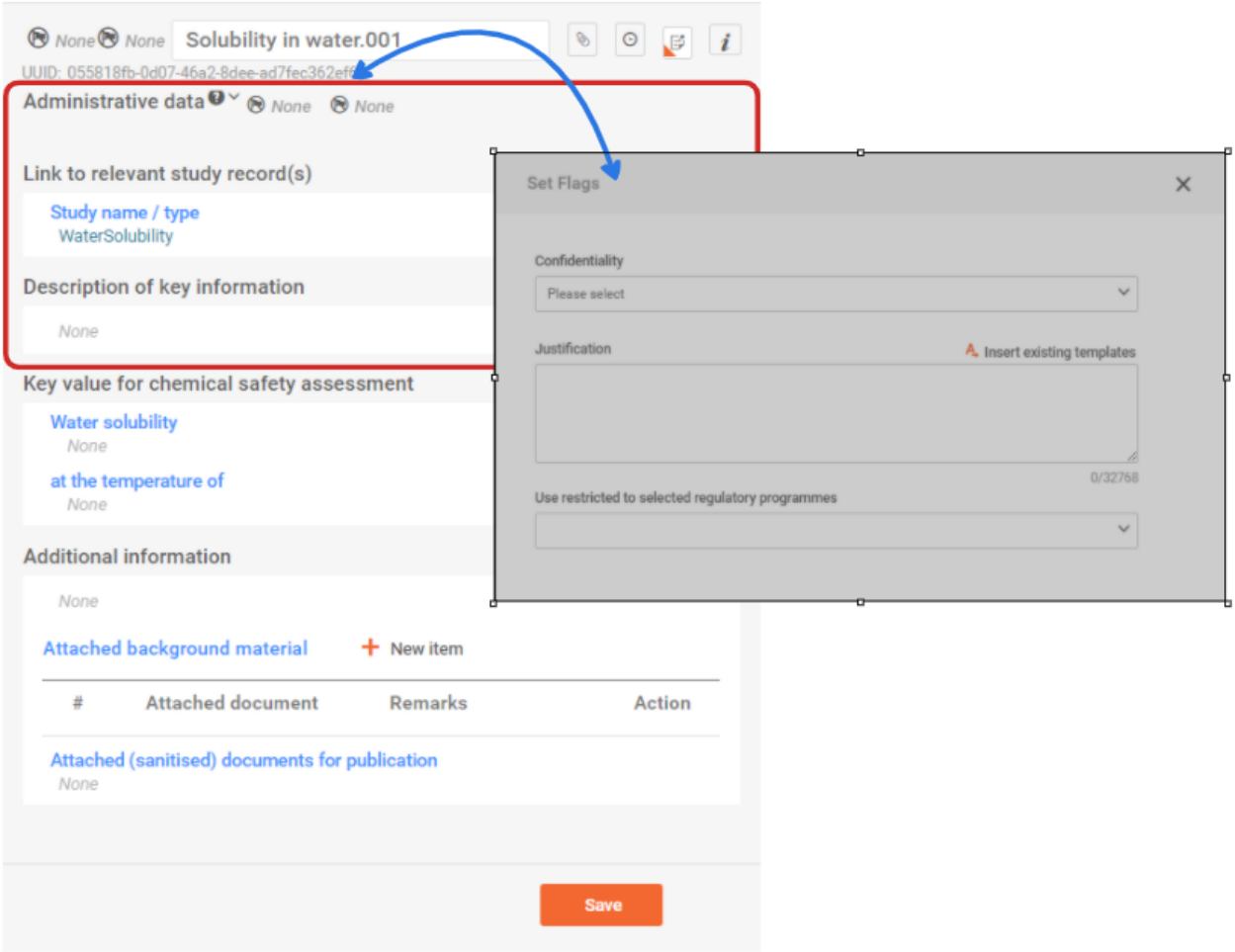
Summary naming – best practices

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
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	AdministrativeDataSummary.DataProtection

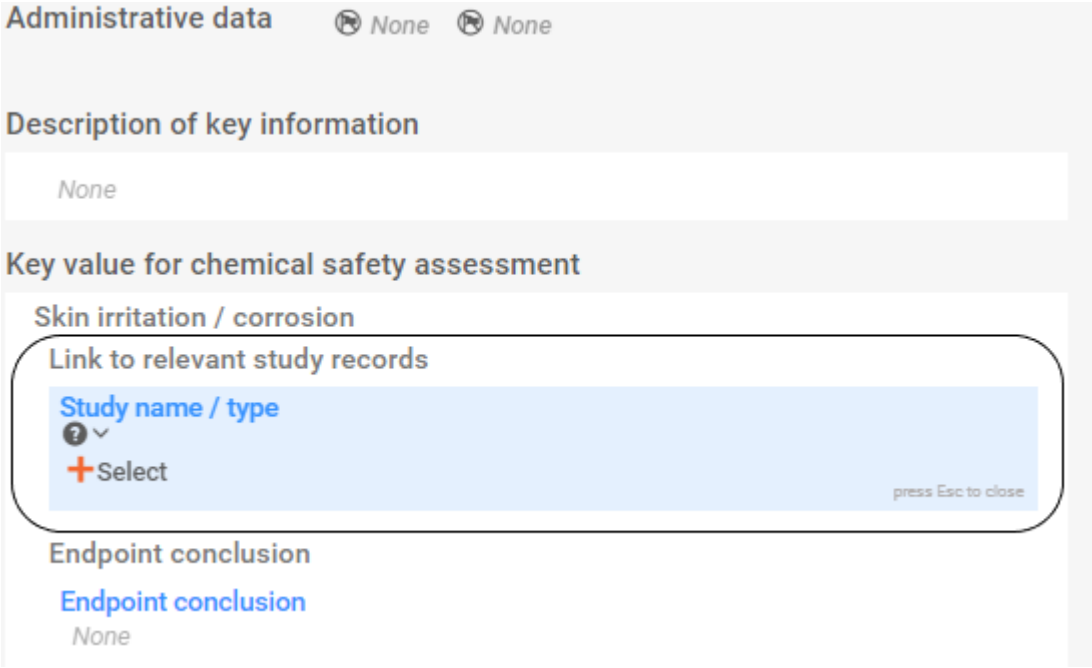
	Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set.		
Link to relevant study record(s)	Provide here the link to the most relevant study(ies) from which the key value for safety assessment is extrapolated.	Header 1	LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	LinkToRelevantStudyRecord.Link
Results		Read-only	LinkToRelevantStudyRecord.Results
Description of key information	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.	Header 1	KeyInformation
		Rich text area	KeyInformation.KeyInformation



Endpoint summary block for relevant study record

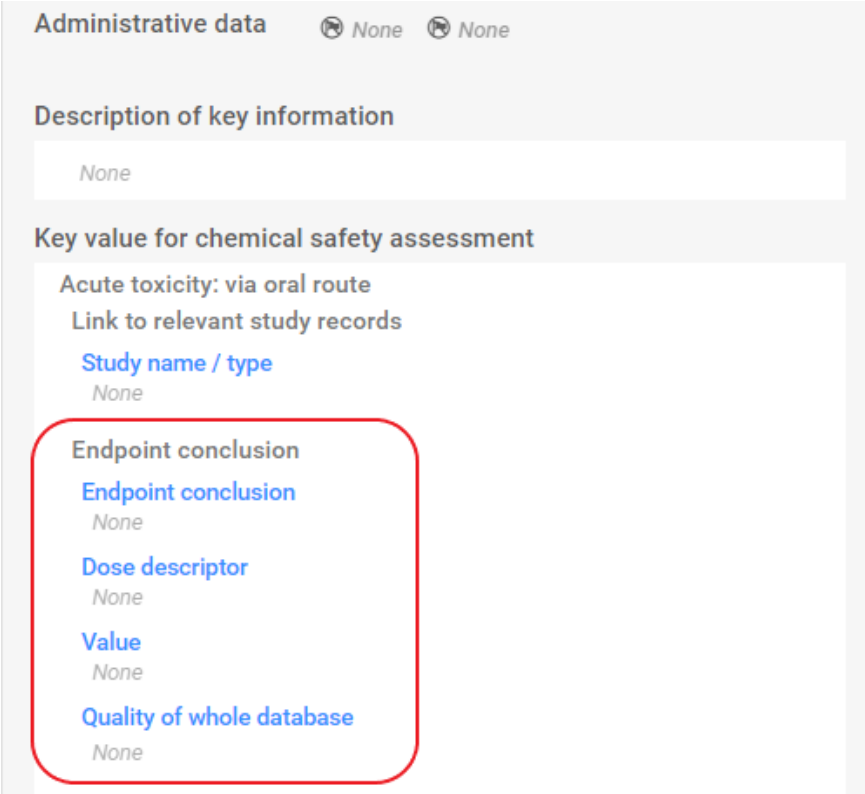
Name	Instructions	Field path
Link to relevant study records		LinkToRelevantStudyRecords
Study name / type	The study giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP. Available epidemiological data	LinkToRelevantStudyRecords.StudyNameType

	are preferred provided that they are reliable and relevant.	
Results		LinkToRelevantStudyRecords.Results



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 reported endpoint study records	Closed list	EndpointConclusion.EffectLevelUnit
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



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
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

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: - 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	Header 1	Discussion

	the sake 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.		
	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 file in Attached (sanitised) documents for publication.	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	Provide any document for publication	Attachments list	Discussion.AttachedSanitisedDocsForPublication

Additional information

None

Attached background material + New item

#	Attached document	Remarks	Action

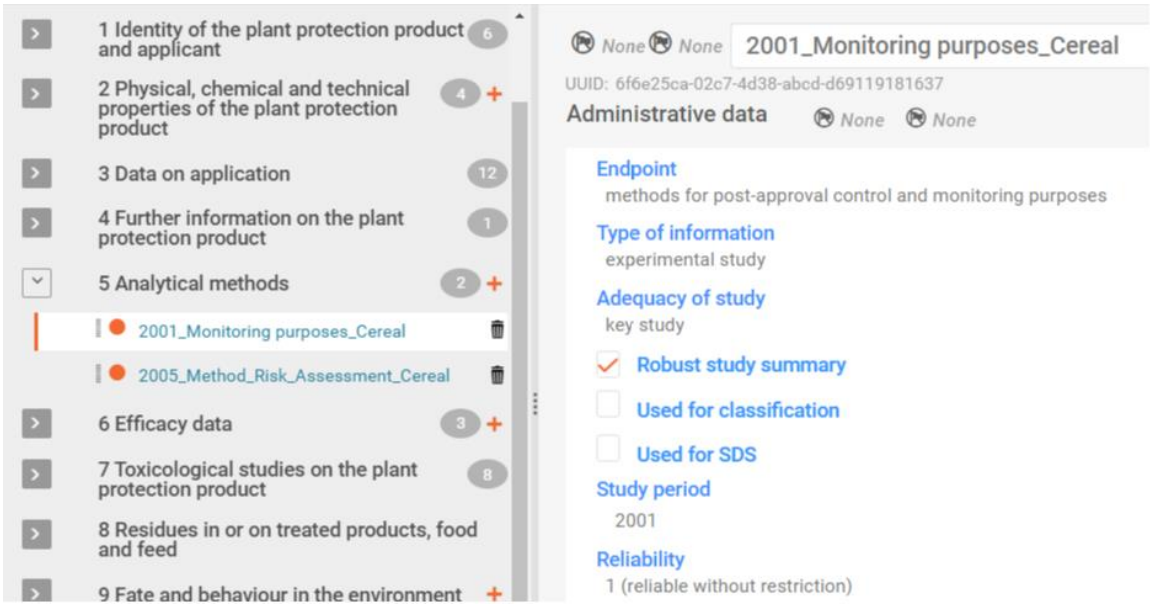
Attached (sanitised) documents for publication

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.'
- 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



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 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.	See Confidentiality of dossiers	AdministrativeData.Data Protection

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. • A **key study** is a study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativeness of data. • 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	Closed list	AdministrativeData.PurposeFlag

	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 For each data requirement at least one 'key study' or two records identified as 'weight of evidence' is expected unless data waiving has been indicated. Where 'key study' or 'weight of evidence' is selected, the Validation assistant checks for document completeness.		
Robust study summary	Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust	Check box	AdministrativeData.RobustStudy

	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.		
Used for classification	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.	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 was conducted, i.e. start and end date. For 'Notified' studies this should be after the date of notification	Text	AdministrativeData.StudyPeriod
Reliability	The term reliability defines the inherent quality of a test report or publication. 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	Open list	AdministrativeData.Reliability

	assignable). The "other:" option may be selected if this scoring system is not used. Studies indicated as key study must have a reliability score of 1 or 2. The validation check will verify consistency between 'Adequacy of study' field and 'Reliability' field (EU_PPP_007, EU_PPP_003). Further explanations on the reliability assessment can be provided in the 'Rationale for reliability incl. deficiencies' field. For further details on reliability please consult the EFSA guidance. 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.		
Rationale for reliability incl.	Describe the rationale for the reliability score	Open list with remarks (32000)	AdministrativeData.RationalReliability

deficiencies	chosen considering the possible impact of deficiencies and/or implications on test results. 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. When assessing an older study against the current guideline, the current guideline can be specified in this field Standard justifications from picklist may be sufficient in some cases. Otherwise select 'Other' and provide for additional explanation in the 'Remarks' field.		
Data waiving	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). Select the reason for data waiving or other and provide a justification in 'Justification for data waiving' field.	Closed list	AdministrativeData.Data Waiving
Justification for data waiving	In addition to the more generic justification	Multi select open list with remarks (32000)	AdministrativeData.Data WaivingJustification

	selected in the preceding field 'Data waiving', it is possible to provide here a more detailed justification. 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'. Otherwise select 'other:' and enter free text. Validation check will flag uncomplete compiling (EU_PPP_002).		
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	In case the study has been reported for another data requirement use cross reference to link to the study to this section. The creation of duplicate versions of		AdministrativeData.CrossReference

	endpoint studies should be avoided		
Reason / purpose for cross-reference		Open list with remarks	AdministrativeData.CrossReference.ReasonPurpose
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

Guidance on the use of the weight of evidence approach in scientific assessments
https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4971

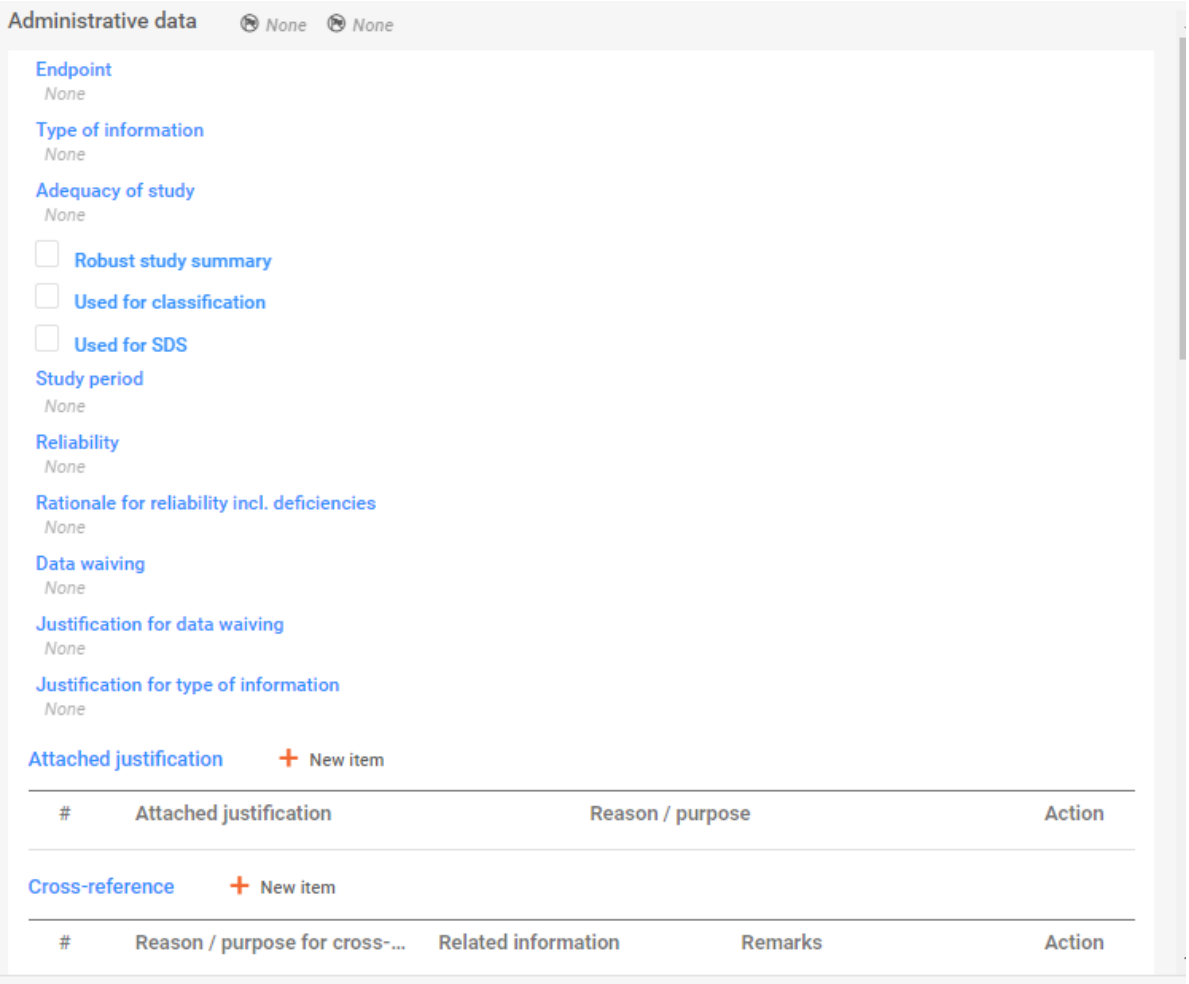
Guidance on the assessment of the biological relevance of data in scientific assessments
https://doi.org/10.2903/j.efsa.2017.4970

Draft of the Scientific Committee guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments. EFSA Journal, EFSA Scientific Committee.
https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2020.6221

Guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal, EFSA Scientific Committee. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4971/full

Principles and process for dealing with data and evidence in scientific assessments. EFSA Journal, European Food Safety Authority. 2015;13(5):4121: 36.
http://www.efsa.europa.eu/en/efsajournal/pub/4121

GUIDANCE DOCUMENT ON PREPARING LISTS OF TEST AND STUDY REPORTS ACCORDING TO ARTICLE 60 OF REGULATION (EC) No 1107/2009



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. This literature reference should also be included in	Literature reference list	DataSource.Reference

	the Data source Reference.		
Data access	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. 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. 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 Open list with remarks DataSource.DataAccess MRL Applications disclosure requirements	Open list with remarks	DataSource.DataAccess

	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 intellectual property rights for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publication in the literature reference entity for scientific assessment purposes only and (b) the relevant bibliographic reference/citation where these publications are available to the public in the literature reference entity for public dissemination on the OpenEFSA portal.		
Data protection claimed	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). In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding	Closed list with remarks	DataSource.DataProtectionClaimed

	study or refer to a document attached that provides justification (e.g. 'for justification see attached document X')		

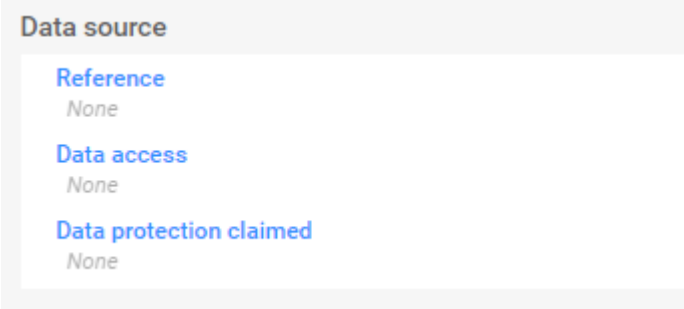


Figure 2.2: Data source block

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 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		Guideline

	one guideline (e.g. US EPA in addition to OECD guideline).		
Qualifier	Select appropriate qualifier, i.e. - '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	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 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'. The method	Open list	Guideline.Guideline

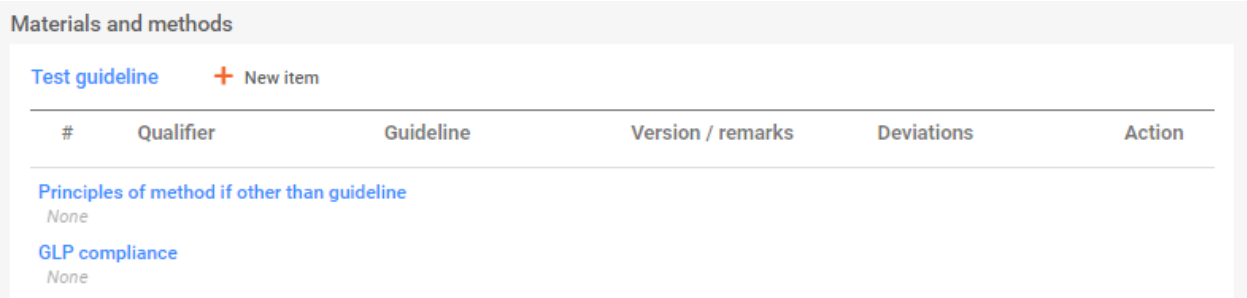
	used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields. Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'.		
Version / remarks	In this text field, you can enter any remarks as applicable, particularly: - 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	Multi-line text	Guideline.VersionRemarks

	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.	Closed list with remarks	Guideline.Deviation
Test guideline			
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' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate. 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. Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available.	Text template	MethodNoGuideline

	Also provide a justification for using this method if appropriate.		
GLP compliance	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.	Closed list with remarks	GLPComplianceStatement
Other quality assurance	Indicate any non-GLP quality assurance system adhered to, if any.	Open list with remarks	OtherQualityAssurance
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

Links to support material:
GEP https://www.eppo.int/ACTIVITIES/plant_protection_products/gep

Communication from the Commission in the framework of the implementation of Commission Regulation (EU) No 283/2013



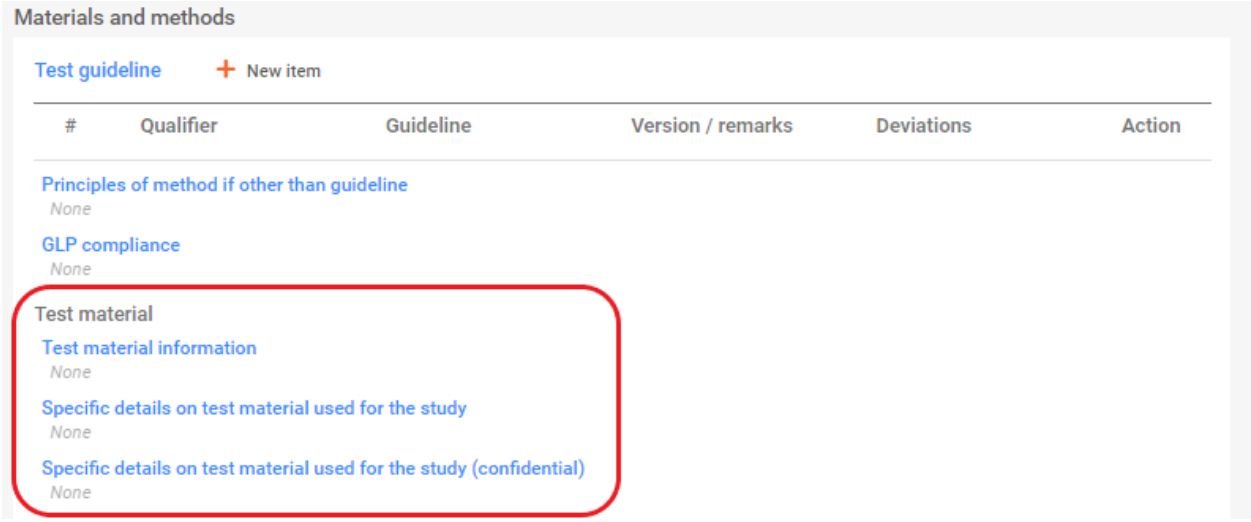
Test material – common block

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 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 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	TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy

	EU REACH) thereof. If applicable, relevant available information on the following items should be given: RADIOLABELLING INFORMATION - Radiochemical purity - Specific activity - Locations of the label - Expiration date of radiochemical substance STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - 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 TREATMENT OF TEST MATERIAL PRIOR TO TESTING - 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) FORM AS APPLIED IN THE TEST (if different from that of starting material) 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. FORMULATED PRODUCT (for	

	biocides/pesticides) 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. OTHER SPECIFICS Provide any other relevant information needed for characterising the tested material.	
Specific details on test material used for the study (confidential)	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-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. If applicable, relevant available information on the following items should be given: RADIOLABELLING INFORMATION - Radiochemical purity - Specific activity - Locations of the label - Expiration date of radiochemical substance STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - Storage condition of test	TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential

	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 TREATMENT OF TEST MATERIAL PRIOR TO TESTING - 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) FORM AS APPLIED IN THE TEST (if different from that of starting material) 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. FORMULATED PRODUCT (for biocides/pesticides) 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. OTHER SPECIFICS Provide any other relevant information needed for characterising the tested material.	



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. - 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).	TestAnimals.OrganismDetails

Test animals

Species
None

Strain
None

Details on species / strain selection
None

Sex
None

Details on test animals or test system and environmental conditions
None

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 information on results incl. tables'. Narrative accompanying such tabular data should mainly address the	Text area	DescriptionIncidenceAnd SeverityObservClinSigns

	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.		
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	ObservDermalIrritationIfDermalStudy
Description (incidence and severity)		Text area	DescriptionIncidenceAndSeverityObservDermalIrritationIfDermalStudy
Dermal irritation		Closed list	ObservDermalIrritation
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	Text area	DescriptionIncidenceAndSeverityObservDermalIrritation

	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 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	DescriptionIncidenceAndSeverityObservBodyweight

	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.		
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. 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	Text area	DescriptionIncidenceAndSeverityObservFoodConsum

	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 efficiency	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	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	Text area	DescriptionIncidenceAndSeverityObservFoodEfficiency

	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	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	DescriptionIncidenceAndSeverityObservWaterConsum
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ObservOphthalm

	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	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	ObservHaematol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description	Text area	DescriptionIncidenceAndSeverityObservHaematol

	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.		
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	Text area	DescriptionIncidenceAnd SeverityObservClinChem

	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.		
Endocrine 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	EndocrineFindings
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. 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	Text area	DescriptionIncidenceAnd SeverityEndocrine

	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.		
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 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	DescriptionIncidenceAnd SeverityObservUrin

	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	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 results and not repeat the details presented in the table(s). NOTE: Depending on	Text area	DescriptionIncidenceAndSeverityObservNeurobehaviour

	the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Immunological 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	ImmunologicalFindings
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	DescriptionIncidenceAndSeverityImmunologicalFindings
Organ weight findings including	Indicate whether any effects were observed	Closed list	ObservOrganWeights

organ / body weight ratios	and whether they were treatment-related or not. Select 'not 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	DescriptionIncidenceAndSeverityObservOrganWeights
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	ObservGrpathol
Description (incidence and	Describe the incidence and severity of effects	Text area	DescriptionIncidenceAndSeverityObservGrpathol

severity)	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.		
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	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	Text area	DescriptionIncidenceAndSeverityObservNeuropathol

	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.		
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	ObservHistopathol
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,	Text area	DescriptionIncidenceAndSeverityObservHistopathol

	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.		
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	Text area	DescriptionIncidenceAndSeverityObservHistopatholNeoplastic

	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.		
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	Text area	DescriptionIncidenceAnd SeverityOtherEffects

	programme some form of a table(s) (predefined table) may be mandatory.		
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	DetailsOnResults

Results and discussion

Results of examinations

Clinical signs
None

Description (incidence and severity)
None

Mortality
None

Description (incidence)
None

Body weight and weight changes
None

Description (incidence and severity)
None

Food consumption and compound intake (if feeding study)
None

Description (incidence and severity)
None

Food efficiency
None

Description (incidence and severity)
None

Water consumption and compound intake (if drinking water study)
None

Description (incidence and severity)
None

Ophthalmological findings
None

Description (incidence and severity)

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	Check box	Efflevel.KeyResult

	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.		
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	Open list with remarks	Efflevel.BasedOn

	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.		
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: - 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

Effect levels

+ New item

#	Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect level	Remarks on result	Action
1	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
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration	Unit measure with Closed List (Decimal)	TargetSystemOrganToxicity.LowestEffectiveDoseConc

	with significant and/or severe toxic effects on the target organ(s) affected.		
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

Target system / organ toxicity

+ New item

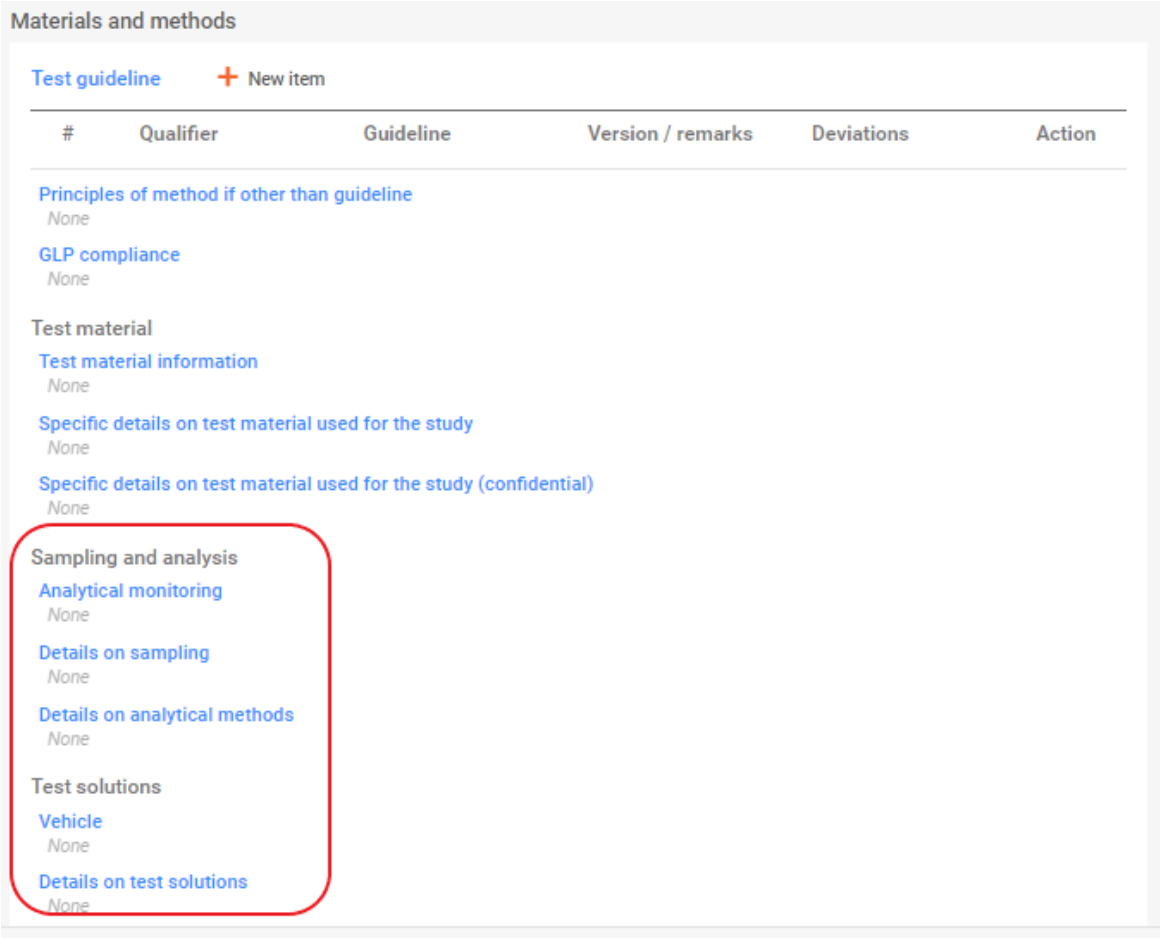
#	Key result	Critical effects o...	Lowest effective...	System	Organ	Treatment related	Dose response r...	Relevant for hu...	Action
1	Key result	None	None	None	None	None	None	None	

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 that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. If a solvent control is included, detail whether a dilution water (procedural) control was also included or omitted.	TestSolutions.DetailsOnTestSolutions

Sampling and analysis / Test solutions BLOCK (OHT: Aquatic tox.)

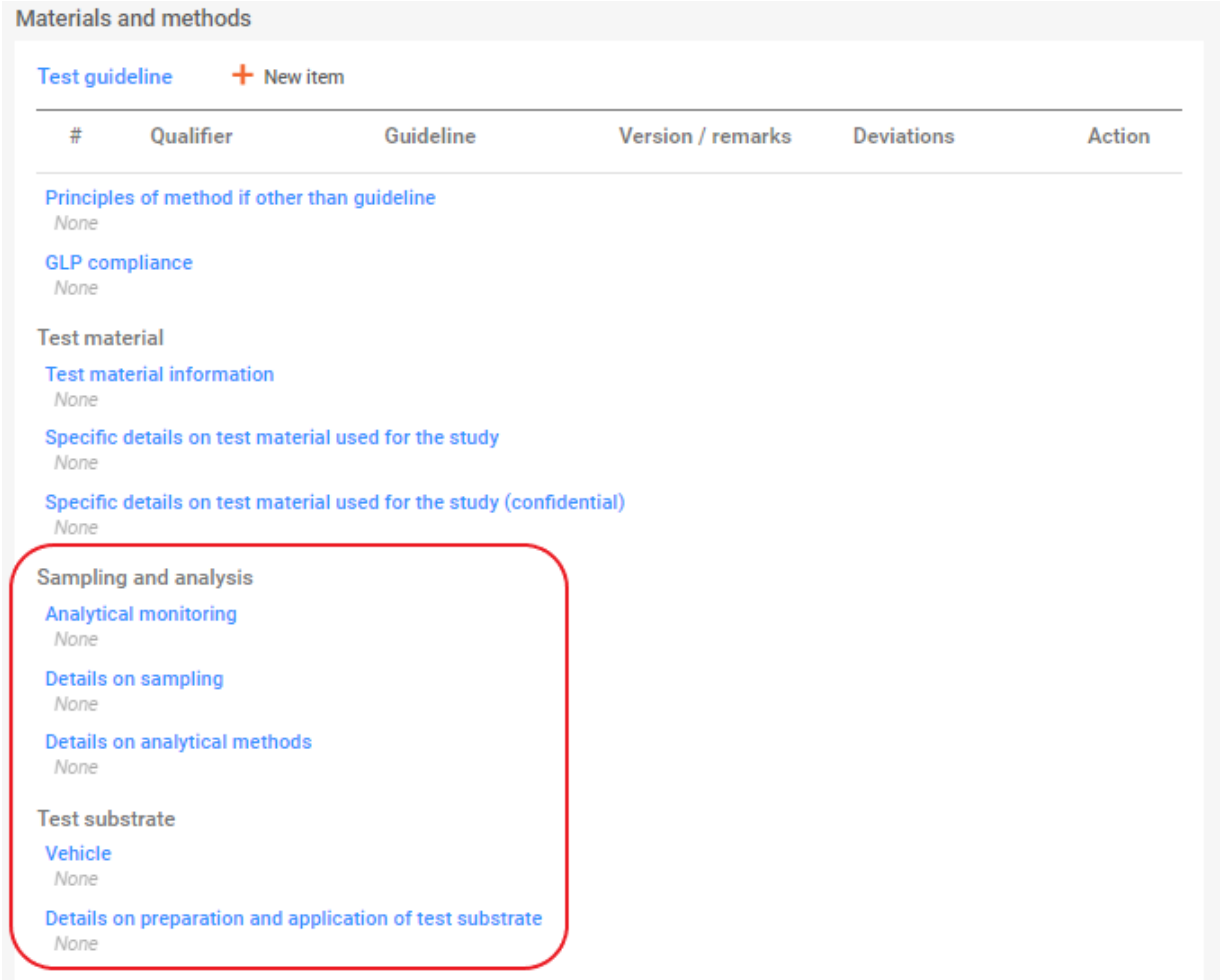
Name	Instructions	Field path
Sampling and analysis		SamplingAndAnalysis
Analytical monitoring	Indicate whether test substance was monitored in the test solutions or suspensions. For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.	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 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, Pesticides NAFTA or EU REACH) thereof. If a solvent control is included, detail whether a dilution water (procedural) control was also included or omitted.	TestSolutions.DetailsOnTestSolutions



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 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.	SamplingAndAnalysis.AnalyticalMonitoring
Details on sampling	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	SamplingAndAnalysis.DetailsOnSampling

	appropriate. Note: Indicate which concentrations were measured if not all. As applicable, provide information for soil, stock and/or spray solution.	
Details on analytical methods	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.	SamplingAndAnalysis.DetailsOnAnalyticalMethods
Test substrate		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'.	TestSubstrate.Vehicle
Details on preparation and application of test substrate	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, Pesticides NAFTA or EU REACH) thereof.	TestSubstrate.DetailsOnPreparationAndApplicationOfTestSubstrate



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
Post exposure observation period	Indicate the post-observation period if appropriate.	StudyDesign.PostExposureObservationPeriod

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

Study design

Test type
None

Study type
None

Substrate type
None

Limit test
None

Total exposure duration
None

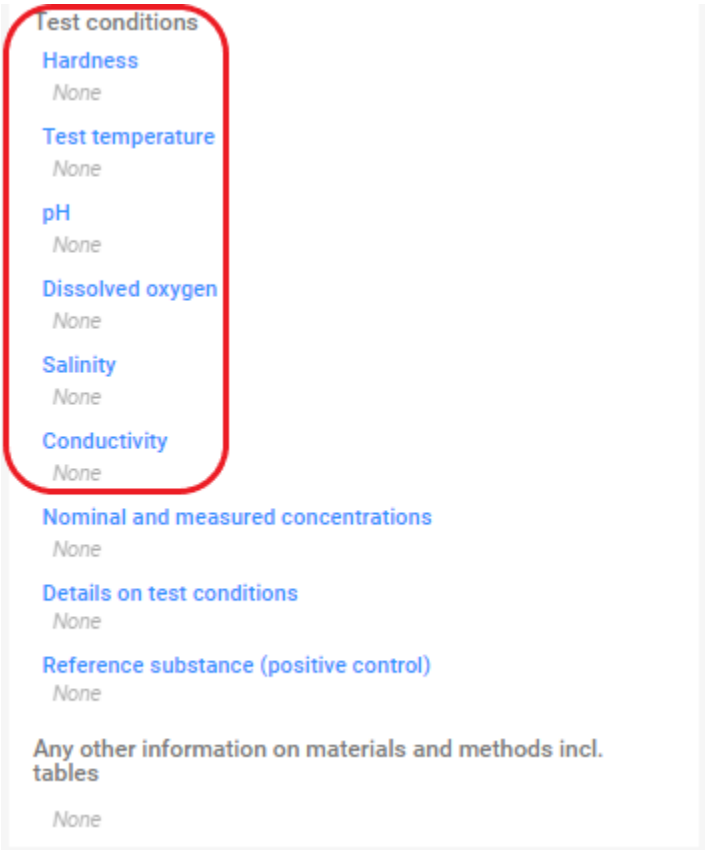
Remarks
None

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 obtained. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich	TestConditions.Ph

	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



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

Test conditions

Test temperature

None

pH

None

Moisture

None

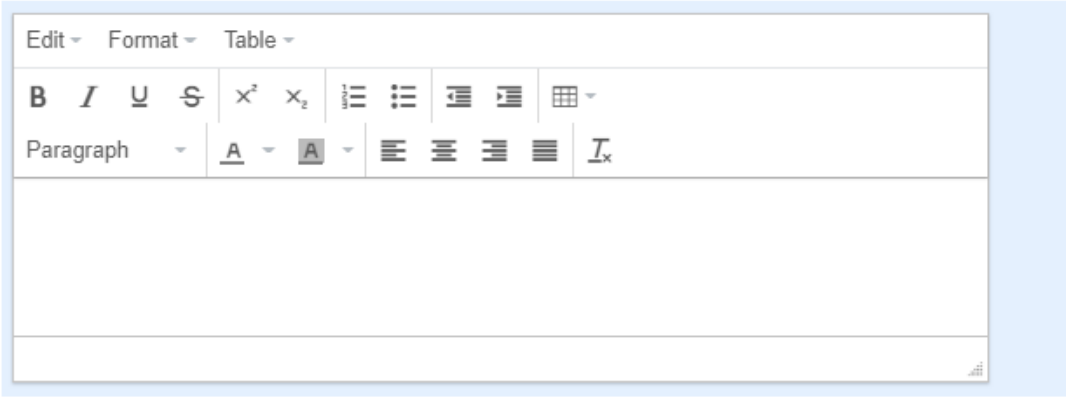
Details on test conditions

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
	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.	AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation

Any other information on materials and methods incl. tables

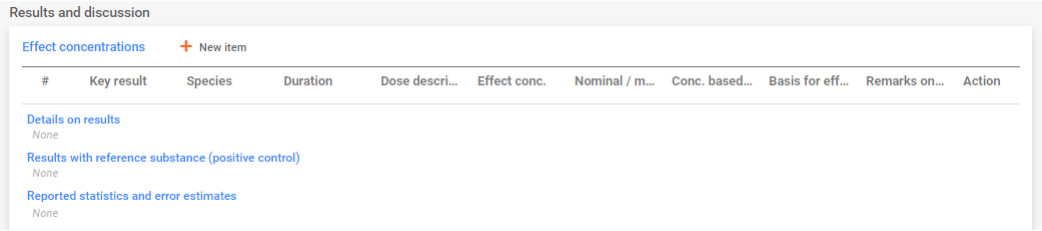


Results and discussion BLOCK (OHT: Aquatic / Terrestrial tox.)

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 equivalent or estimated. Select 'not specified' if not known.	EffectConcentrations.NominalMeasured
Conc. based on	Indicate whether the concentration is based on the test material (test	EffectConcentrations.ConcBasedOn

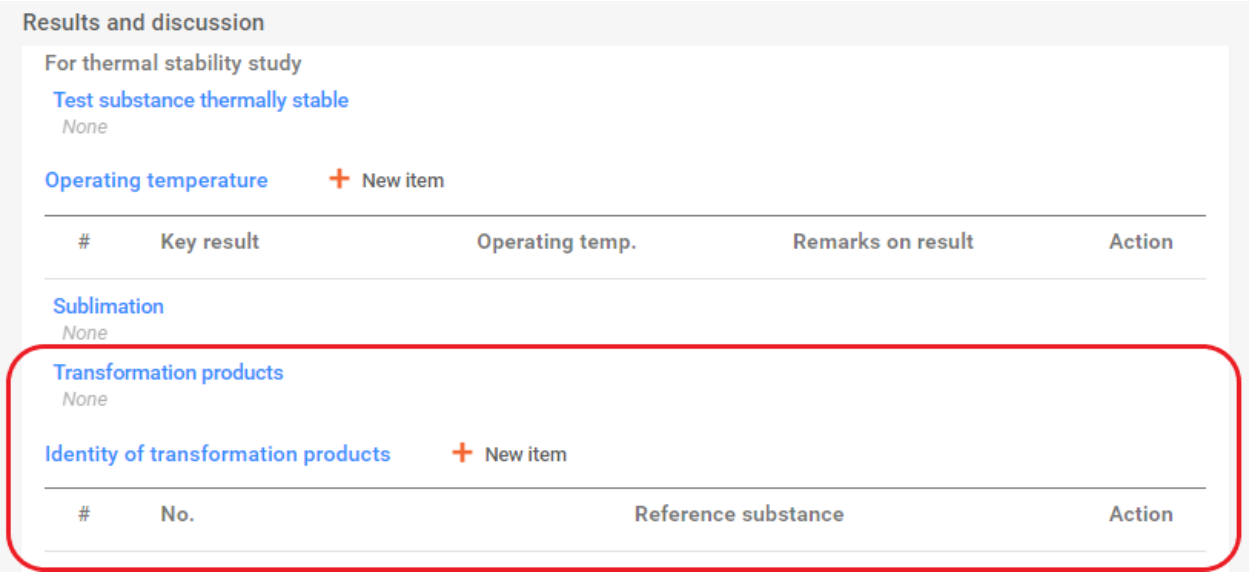
	mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks 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.	
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.BasisForEffectMulti
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'.	EffectConcentrations.RemarksOnResults
Effect concentrations		
Details on results	Briefly summarise relevant	ResultsDetails

	observations and any dose response relationship. Information on toxicity, infectiveness and pathogenicity must be reported. 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.	
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.	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.	Statistics



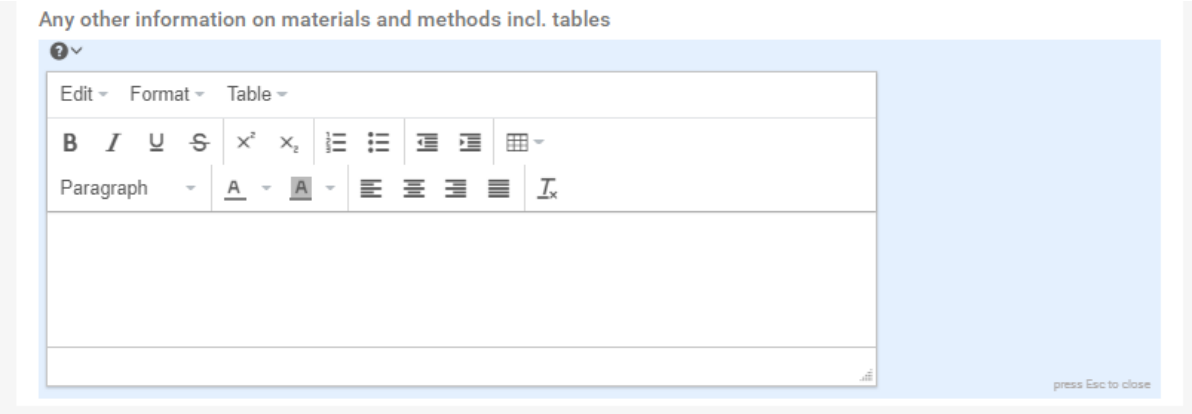
Transformation products BLOCK (OHT)

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		



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

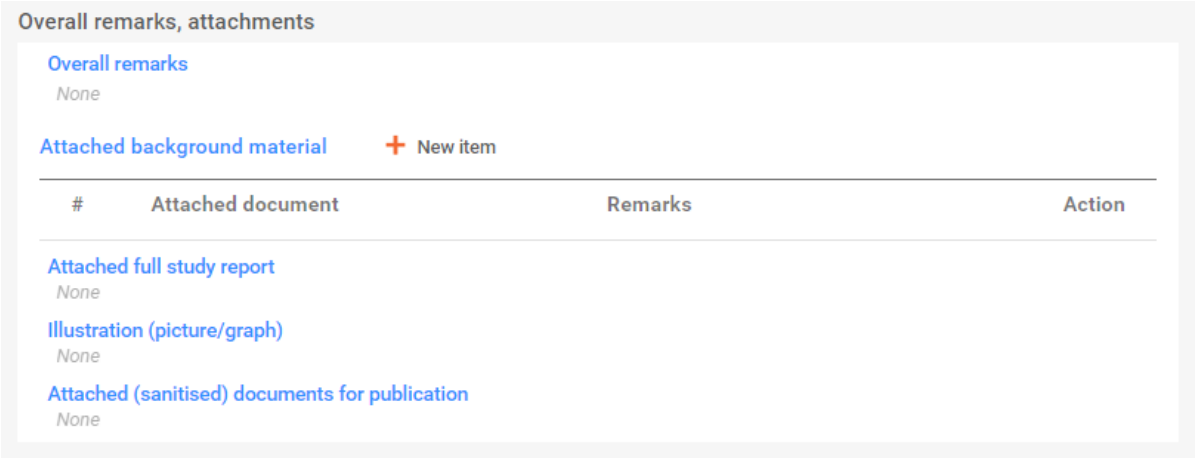


Overall remarks, attachments – common block

Name	Instructions	Type	Field Path
Overall remarks, attachments		Header 1	OverallRemarksAttachments
Overall remarks	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. 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.	Rich text area	OverallRemarksAttachments.RemarksOnResults
Attached background material	Attach any background document that cannot be inserted in any rich		OverallRemarksAttachments.AttachedBackgroundMaterial

	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	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). 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. 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.	Single file attachment	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	OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
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.IllustrationPicGraph
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



Applicants summary and conclusion – common block

Name	Instructions	Type	Field Path
Applicant's summary and conclusion		Header 1	ApplicantSummaryAndConclusion
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 justification in field 'Rationale for reliability incl. deficiencies' as to why this study summary is considered reliable.	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 (UN GHS). Further explanations can be	Closed list with remarks (2000)	ApplicantSummaryAndConclusion.InterpretationOfResults

	entered in the supplementary remarks field. 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.		
Conclusions	This field should be used to summarise the conclusions by the applicant and will be used in study summaries produced using report generator.	Text area	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	ApplicantSummaryAndConclusion.ExecutiveSummary

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 justifications in the picklist apply,	All endpoint study records	Administrative data – common block

		select 'other:' and provide the justification in the below field. 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.		
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
QLT_PPP_004: Reference must be provided for KS and WoE	Quality rules/Warning	'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' the 'Reference' entry	All endpoint study records	Data source (Literature Reference) – common block

		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: <Display dynamic message depending on selection in 'Reference type' field> #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. #other company data# - 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'.		

		# 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. #other: or no selection# <Merge and display all the above>		
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 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	All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms	Material and methods – common block

		provide information on the guideline in the below field. 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'.		
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, 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. The TMI record should contain sufficient information to allow the understanding of the identity of the	All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTarget Organisms	Test material – common block

		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. For a read-across target record, the test material information should identify the target substance of the read-across.		
QLT_PPP_007: Key studies should have reliability 1 or 2	Quality rules/Warning	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	All endpoint study records	Administrative data – common block

		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.		
QLT_PPP_008: Deviations in the guideline must be explained	Quality rules/Warning	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 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.	All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTarget Organisms	Material and methods – common block

QLT_PPP_009: Attached (sanitised) documents for publication must be provided for KS/WoE (all ESR)	Quality rules/Warning	'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 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.	All endpoint study records	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	All endpoint study records	Literature reference

		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 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_SUMMARY.EffectivenessAgainstTargetOrganisms ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms ENDPOINT_SUMMARY.AnalyticalMethods ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans ENDPOINT_SUMMARY.Sensitisation ENDPOINT_SUMMARY.AcuteToxicity ENDPOINT_SUMMARY.SpecificInvestigationsOtherStudies ENDPOINT_SUMMARY.GeneticToxicity ENDPOINT_SUMMARY.RepeatedDoseToxicity ENDPOINT_SUMMARY.AdditionalToxicologicalInformation ENDPOINT_SUMMARY.MigrationOfResiduesIntoAndTheirBehaviourOnFoodOrFeedingstuffs ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs ENDPOINT_SUMMARY.MagnitudeResiduesPlants ENDPOINT_SUMMARY.NatureMagnit	N/A

			udeResiduesProcessedCommodities ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs ENDPOINT_SUMMARY.EnvironmentalFateAndPathways ENDPOINT_SUMMARY.AdditionalInformationOnEnvironmentalFateAndBehaviour ENDPOINT_SUMMARY.BiodegradationInSoil ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests ENDPOINT_SUMMARY.PhototransformationInAir ENDPOINT_SUMMARY.OtherDistributionData ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP ENDPOINT_SUMMARY.AquaticToxicity ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP ENDPOINT_SUMMARY.LongTermToxicityToAquaticInver	

			tebrates_EU_PPP ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP ENDPOINT_SUMMARY.ToxicityMicroorganisms ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP ENDPOINT_SUMMARY.AdditionalEcotoxicologicalInformation ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP	
QLT_PPP_015: KS/WoE must be provided for all required sections (Mixture_MO)	Quality rules/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	

		- 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. *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'.*		
QLT_PPP_016: Summaries must be provided for all required sections (Mixture_MO)	Quality rules/Warning	*Section <x.x>: At least one endpoint study summary must be provided for this section.*	ENDPOINT_SUMMARY.PhysicalChemicalProperties ENDPOINT_SUMMARY.GeneralInformation ENDPOINT_SUMMARY.StabilityThermal ENDPOINT_SUMMARY.StorageStability ENDPOINT_SUMMARY.Explosiveness ENDPOINT_SUMM	

			ARY.OxidisingProperties ENDPOINT_SUMMARY.FlashPoint ENDPOINT_SUMMARY.Flammability ENDPOINT_SUMMARY.AutoFlammability ENDPOINT_SUMMARY.pH ENDPOINT_SUMMARY.Viscosity ENDPOINT_SUMMARY.SurfaceTension ENDPOINT_SUMMARY.AdditionalPhysicoChemical ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms ENDPOINT_SUMMARY.AnalyticalMethods ENDPOINT_SUMMARY.Efficacy ENDPOINT_SUMMARY.AdditionalToxicologicalInformation ENDPOINT_SUMMARY.AcuteToxicity ENDPOINT_SUMMARY.IrritationCorrosion ENDPOINT_SUMMARY.Sensitisation ENDPOINT_SUMMARY.EcotoxicologicalInformation ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP ENDPOINT_SUMMARY.AquaticToxicity	

			ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP ENDPOINT_SUMMARY.ShortTermToxicityAquaInvert_EU_PPP ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP ENDPOINT_SUMMARY.ToxicityTerrestrialArthropods_EU_PPP ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP	
QLT_PPP_021: At least one Mix Composition must exist with linked Active (Substance)_PPP_All_Submissions	Quality rules/Warning	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'.	FLEXIBLE_RECORD.MixtureComposition	N/A

QLT_PPP_022: At least one valid constituent must exist (for each Active substance) All_EU_PPP	Quality rules/Warning	For each Active substance composition, at least one constituent must be defined. All constituents must be identified by linking a reference substance.	FLEXIBLE_RECORD.MixtureComposition FLEXIBLE_RECORD.SubstanceComposition	N/A
QLT_PPP_023: At least one LE composition must exists in Active subsatance dataset_Only Active sub.	Quality rules/Warning	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 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.	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition	N/A
QLT_PPP_024: each (active) substance must have a reference substance in section 1.1 All_EU_PPP	Quality rules/Warning	A reference substance must be linked in IUCLID section 1.1.	1.1_Identification FLEXIBLE_RECORD.MixtureComposition SUBSTANCE	N/A

QLT_PPP_025: All Active substances must be the same (same UUID)_ All_PPP	Quality rules/Warning	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.	1.1_Identification FLEXIBLE_RECORD.MixtureComposition SUBSTANCE	N/A
QLT_PPP_026: at least one GAP must be created in All_PPP	Quality rules	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 application - Growth stage is mandatory if GAP refers to a crop; if GAP refers to treatment of non-crop objects (children of	FLEXIBLE_RECORD.GAP	N/A

		3NOCFO) or to children codes of 3CRPAO (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').		
QLT_PPP_027: Exactly one literature reference must be provided in KS, WoE ESRs_All_EU_PPP	Quality rules	'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	All endpoint study records	Literature reference

		'Year' or the 'Report date' must always be indicated. In addition, as a minimum, the following must be provided: - 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 from a literature source, the field 'Bibliographic source' must be provided. Sufficient information should be given to be able to identify the literature source.		
QLT_PPP_029: All constituents in the first composition record in Active	Quality rules/Warning	Multiple constituents in the active substance composition/purity specification are	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComp	N/A

substance must represent distinct substance identities_All_PPP		identified with the same reference substance. Remove the duplicate entries.	osition	
EU_PPP_034: European reference number must be provided in UUID format (MRL)	Business rule, Failure	Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.		N/A